



**Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure
Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment
Determinations**

First Biannual (B1), 2026 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding determination for each application processed in CMS' First Biannual 2026 Non-Drug and Non-Biological Items and Services HCPCS Level II code application review cycle. Each summary includes the Medicare Electronic Application Request Information System™ (MEARIS™) identification number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS Level II coding recommendation; a summary of public feedback from or following the HCPCS Level II public meeting; CMS' final HCPCS Level II coding determination, as well as CMS' preliminary and final benefit category and payment determination, if applicable.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS Level II determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73860) is available at <https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues>.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B. When the item is not excluded from coverage by statute and is found to fall within a benefit category, CMS needs to determine what payment rules apply to the item if other statutory criteria for coverage of the item are met. DMEPOS payment categories with corresponding HCPCS pricing indicator codes are included in the Appendix. All new coding actions will be effective October 1, 2026, unless otherwise indicated.

The HCPCS Level II coding determinations below will also be included in the October 2026 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

Table of Contents

HCPCS Level II coding, Medicare benefit category, and Medicare payment determinations from the HCPCS Level II public Meeting on Monday, June 1, 2026.

1. HCPCS Level II Codes for Various FDA Approvals under a 505(b)(2) or Biologics License Application (BLA) Pathways and Products “Not Otherwise Classified” - HCP220517FAENJ.....	5
2. Amoena Adapt Air™ - HCP2512297920D.....	8
Amoena Adapt Air™ Contact - HCP251224RRB5M.....	11
Amoena Custom Adapt Air™ - HCP251224XANLD	14
3. Veristra™ - HCP251230VLMD5	16
4. MenHealth - HCP25122927P00	18
5. Splashblocker® - HCP260102FQ98X.....	21
6. RevoFit® Lamination Kit - HCP260102PP5Y4.....	25
7. DermiSphere™ hDRT - HCP260102TL8N8	31
8. Fibrillar Collagen Wound Dressing - HCP251223WGYKB.....	32
9. CAVEO - HCP260102Y53F7	34
10. Expandable Rolling Bathtub- HCP250723QJMX.....	36
11. Halo Safety Wing - HCP250924CN7H4	39
12. ATMOS C051 - HCP251007KCNJC	41
13. Gradient Compression Glove - HCP260102UYFD8.....	45
14. UrgoK2 Lite (Ankle Circumference of 9 3/4"- 12 1/2") - HCP2512315R8FJ	47
UrgoK2 Lite (Ankle Circumference of 7 1/8"- 9 3/4") - HCP251231FDGRY	50
UrgoK2 (Ankle Circumference of 9 3/4"- 12 1/2") - HCP2512311TPQC.....	53
UrgoK2 (Ankle Circumference of 7 1/8"- 9 3/4") - HCP251231WNJ3Q.....	56
15. Synchrony® - HCP2601028L5RB	59
16. Sternum Protector - HCP251229E0XN7	66
17. CoreTech® Sternocostal Orthosis - HCP2512301TRQK	70
18. Permeaderm® Glove - HCP2512242FV8T.....	74
19. LacertaMatrix - HCP251229N10KE	76
20. PuraPly® MZ - HCP251231TLX93	77
21. Theracor™ - HCP251230XHUL4.....	79
22. Carbon Life - HCP251112EUXTE.....	80
23. DermaBind SL Optic™ - HCP2510282XA05	82
24. AmchoMatrix - HCP251223WL54Y.....	84
25. Ceragem Master V6 - HCP260101KNV3E.....	86
26. Cool Cube™ - HCP251218D9JD7	89
27. Kangaroo OMNI™ Thick Formula ENTelliSet and Kangaroo OMNI™ Thick Formula ENTelliSet with Flush Bag - HCP251231TWH4Q	91
28. VYAFUSER™ Pump - HCP2508144JR8W	94
Supplies for Device-Drug Combination Infusion Pump - HCP250814QVQD0.....	97
29. NTI-duo - HCP2507125MV9M	100
30. Eneura Single-Pulse Transcranial Magnetic Stimulation (sTMS) Neuromodulation System - HCP250812GVKKD	103
31. ExoBand - HCP251230KVQK3.....	106
32. Ankle Foot Orthosis - HCP251211GM5MA.....	109

33. Omni-Directional Shank/Foot System - HCP251210K9WKV	112
34. Rollz Motion - HCP240628PHWKW	115
35. NeuRx® Diaphragm Pacing System External Pulse Generator - HCP26010276W44 ..	118
NeuRx® Diaphragm Pacing System Alkaline Battery - HCP26010255JNV	121
NeuRx® Diaphragm Pacing System Lithium Battery - HCP260102EDYL9	124
NeuRx® Diaphragm Pacing System Test Plug - HCP260102G41KN	127
NeuRx® Diaphragm Pacing System Connector Holder - HCP260102TFEED	128
NeuRx® Diaphragm Pacing System Surface Electrode Pad - HCP2601020JMFD.....	131
NeuRx® Diaphragm Pacing System Surface-Electrode Interconnect - HCP2601026P96	134
NeuRx® Diaphragm Pacing System Strain Relief Boot - HCP2601024LG5F.....	137
NeuRx® Diaphragm Pacing System Patient Cable - HCP260102A063D	140
NeuRx® Diaphragm Pacing System Electrode Connector Socket Kit - HCP2601025KXFL	143
36. NeuRx® Diaphragm Pacing System Patient Kit - HCP260102XDWK0.....	145
37. FSYX™ Ocular Pressure Adjusting Pump - HCP2501014576E	147
FSYX™ Ocular Pressure Adjusting Goggles - HCP250101BJQNN.....	151
38. Appendix A: DMEPOS Payment Categories	154

HCPCS Level II Codes for Various FDA Approvals under a 505(b)(2) or Biologics License Application (BLA) Pathways and Products “Not Otherwise Classified” - HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS’ Fourth Quarter (Q4) of 2025 and First Quarter (Q1) of 2026 Drug and Biological HCPCS code application review cycles, per our postings at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/PriorYearsCMSHCPCSLevelIII-Coding-Decisions-Narrative-Summary>.

Summary of Applicant's Submission

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under a 505(b)(2) New Drug Application (NDA) or a BLA after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration’s (FDA) Orange Book and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS Level II codes as described at the following CMS link: <https://www.cms.gov/files/document/frequently-asked-questions-single-source-drugs-and-biologicals.pdf>, CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of “single source drug” in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of “multiple source drug” in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS Level II code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk² to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Determination

We established or revised 3 HCPCS Level II codes within the Q4 2025 and 17 HCPCS Level II codes within Q1 2026 to separately identify products approved by the FDA after October 2003 and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

See Appendix A for a complete list of new HCPCS Level II codes that we are establishing.

CMS intends to continue our review in subsequent HCPCS Level II code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003 and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified”.

Summary of Public Feedback

Many commenters disagreed with CMS’ proposed list of HCPCS Level II coding changes. We received over twenty written and verbal comments from various manufacturers, providers, and advocacy groups, and they all shared a common concern that the proposed immune globulin HCPCS Level II coding and unit changes would create significant administrative disruption across the healthcare system, while offering little to no meaningful clinical, financial, or operational benefit. They stated that providers, payers, manufacturers, and vendors would be forced to simultaneously redesign billing systems, prior authorization workflows, payer configurations, claims processing systems, reimbursement structures, electronic medical records, inventory management systems, reporting tools, and operational procedures. Commenters emphasized that providers already operate under extensive utilization management requirements, including documentation of medical necessity, diagnosis validation, insurance authorization, and compliance monitoring. As a result, they questioned the problem this proposal is intended to solve, noting that providers who are already following clinical guidelines and responsibly managing utilization are not the source of any identified concerns.

Most commenters emphasized the potential impact on care, particularly for individuals with rare and chronic diseases who rely on immune globulin therapies. Commenters stressed that continuity of care must remain the highest priority and warned that even short treatment interruptions could have serious consequences. They explained that beneficiaries already face uncertainty at the beginning of each year due to insurance benefit resets, formulary changes, network changes, and annual reauthorization requirements. They stated that adding nationwide coding and unit restructuring during this period could overwhelm providers and payers, increasing the likelihood of authorization delays, claim denials, payment disruptions, and ultimately interruptions in treatment. Several commenters noted that a missed dose could result in significant health setbacks and, in some cases, prolonged hospitalizations.

The commenters also questioned the rationale behind the proposed dose description unit changes. While CMS appears to be pursuing greater billing standardization through smaller billing units, they stated that immune globulin dosing is based on individual weight and clinical need, meaning the actual amount of drug administered would not change. Instead, providers would simply bill a larger number of units for the same dose. For example, doses currently billed in 500 mg units could require hundreds of additional billing units under the proposed 100 mg or 200 mg structure. Commenters expressed concern that these larger unit counts would increase the likelihood of medically unlikely edit denials, unit conversion errors, authorization mismatches, billing mistakes, and reimbursement delays. They also noted that using different

billing units across products would create additional complexity and increase the risk of confusion among providers and payers.

Another concern among the commenters was the effective and implementation date of January 1, 2027. The commenters described January as the most operationally challenging period of the year due to insurance renewals, benefit verification activities, formulary updates, and reauthorization processing. They warned that implementing major coding and billing changes during this period would significantly increase administrative burden and elevate the risk of access disruptions. Commenters stated that the healthcare industry would not have sufficient time to safely operationalize the changes and urged CMS to select a different implementation date.

The commenters requested substantial implementation safeguards if CMS ultimately decides to proceed. These included delaying implementation until at least 2028, providing an extended transition period of at least 18 months, allowing a minimum of six months between publication of final HCPCS Level II codes and implementation, protecting existing prior authorizations, ensuring payer readiness, and issuing clear operational guidance. One commenter also recommended that CMS adopt a consistent 100 mg dose description across all affected products and reevaluate current unit limits to reduce the risk of unnecessary denials. However, commenters generally supported removing references to "subcutaneous" or "intravenous" from the HCPCS Level II code descriptors.

Overall, the commenters maintained that these dose revisions would impose widespread operational burdens and create risks to access without generating meaningful improvements in clinical oversight, reimbursement accuracy, or cost savings.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published determination. After consideration of the comments we received, at this time CMS will maintain the 500 mg dose description for HCPCS Level II codes describing immune globulin products while we continue to consider whether the lowest dose description is needed for more accurate billing of administered and discarded amounts of these products.

Amoena Adapt Air™ - HCP2512297920D

Topic/Issue

Request to establish a new HCPCS Level II code to identify Amoena Adapt Air™.

Applicant's suggested language: LXXXX, "External breast prosthesis, full, silicone, with integral adjustable air-chamber system for individualized volume and contour modification, without self-adhesive backing, any type, each"

Summary of Applicant's Submission

Amoena USA submitted a request to establish a new HCPCS Level II code to identify Amoena Adapt Air™. Amoena Adapt Air™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Amoena Adapt Air™ is a full external silicone breast prosthesis designed with air-chamber technology, allowing precise and individualized adjustment of prosthesis volume and projection. The product features a soft matte silicone membrane, InTouch Light silicone that reduces weight by 25–40 percent and an individually adjustable back that conforms closely to uneven chest walls. The prosthesis functions as a non-custom external replacement for missing breast tissue following mastectomy or breast conserving surgery. The adjustable air chamber allows the user to fine tune volume and projection to improve symmetry, fit, comfort, and weight distribution. Amoena Adapt Air™ is worn daily inside a pocketed mastectomy bra.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code L8030, "Breast prosthesis, silicone or equal, without integral adhesive" to instead read "Breast prosthesis, silicone or equal, without integral adhesive, any type" to describe Amoena Adapt Air™.

Amoena Adapt Air™, a silicone breast prosthesis that allows individualized adjustment of prosthesis volume and projection without self-adhesive backing is similar to other products in HCPCS Level II code L8030.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8030 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8030 is \$430.74.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Amoena USA disagreed with CMS' preliminary determinations. The commenters stated that Amoena Adapt Air™ features an integrated air chamber that allows for post-fit volume adjustment, a clinically distinct capability that is not captured by any existing HCPCS Level II code. This feature addresses the needs of individuals experiencing anatomical changes due to weight fluctuation, post-surgical edema, or radiation effects. Given this functionality, the commenter proposed a new HCPCS Level II code with an initial allowable amount of \$625, representing approximately a 40 percent premium over the comparable baseline of approximately \$445 for HCPCS Level II code L8030. The commenter stated that this pricing is supported by component cost differentials, wholesale and retail pricing data, and fitter labor considerations, with a gap-fill review recommended following one complete reporting cycle is not comparable to standard prefabricated silicone prostheses and payment should instead be gap-filled using verifiable commercial pricing. A commenter stated that the higher cost of these items is justified by unique features and by macroeconomic pressures such as silicone supply fluctuations, labor and mining costs, and geopolitical factors, which have driven production costs up approximately by 50 percent since year 2020.

Amoena USA further clarified that the price of roughly \$450 mentioned during the public meeting was a suggested retail price used for presentation purposes only and acknowledged that manufacturer suggested retail prices are not an appropriate basis for establishing Medicare payment amounts. Instead, the commenter requested gap-fill payment amount grounded in verifiable commercial pricing and documented cost information, reflecting the higher acquisition cost and market value of their product relative to standard silicone breast prostheses.

The commenter also clarified a prior statement from the public meeting. The intent was never to suggest CMS to re-price using Medicare claims or billing data, but rather that Amoena USA would submit updated verifiable supplier and commercial pricing after one full update cycle to allow CMS to confirm or adjust the amount.

The commenter stated that while Amoena Adapt Air™ have historically been billed under HCPCS Level II code L8030 due to the absence of a better fitting code, this should not be interpreted as confirmation that this code accurately describes the technology and its cost. And that CMS' proposed preliminary determination would permanently fold these adjustable air-chamber devices into a code built for basic prefabricated forms. The commenter stated that HCPCS Level II code L8030 sets the wrong payment for these products. Further, the commenter said that they are not claiming that these products cannot be furnished at the current rate, but rather that the rate creates unsustainable margin pressure on suppliers.

Another commenter emphasized the uniqueness of Amoena USA products, noting that out of everything she has tried, these are the only ones that have met her expectations and left her fully satisfied.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to:

Revise existing HCPCS Level II code L8030, "Breast prosthesis, silicone or equal, without integral adhesive" to instead read "Breast prosthesis, silicone or equal, without integral adhesive, any type" to describe Amoena Adapt Air™.

CMS notes that various Amoena Adapt Air™ products featuring the air-chamber technology have historically been billed under HCPCS Level II code L8030. This billing history supports CMS' determination that the revised descriptor appropriately captures the product.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8030 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8030 is \$430.74.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Amoena Adapt Air™ Contact - HCP251224RRB5M

Topic/Issue

Request to establish a new HCPCS Level II code to identify Amoena Adapt Air™ Contact.

Applicant's suggested language: LXXXX, "External breast prosthesis, full, silicone, with integral self-adhesive backing and adjustable air-chamber technology, customizable volume and contour, any type, each"

Summary of Applicant's Submission

Amoena USA submitted a request to establish a new HCPCS Level II code to identify Amoena Adapt Air™ Contact. Amoena Adapt Air™ Contact is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Amoena Adapt Air™ Contact is a full silicone external breast prosthesis with integrated self-adhesive backing and individually adjustable air-chamber technology. Amoena Adapt Air™ Contact is a lightweight, full-coverage silicone breast form that incorporates a medical-grade adhesive contact surface and an internal inflatable air chamber that allows user to precisely adjust volume, projection, and contour. The prosthesis functions to replace the shape, weight, and symmetry of the natural breast following mastectomy while providing individualized adaptation to uneven chest walls, surgical irregularities, lymphedema-related changes, or weight fluctuation. Its self-adhesive design provides secure support and natural movement without reliance solely on a bra pocket.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code L8031, "Breast prosthesis, silicone or equal, with integral adhesive" to instead read "Breast prosthesis, silicone or equal, with integral adhesive, any type" to describe Amoena Adapt Air™ Contact.

Amoena Adapt Air™ Contact, a silicone breast prosthesis that allows individualized adjustment of prosthesis volume and projection with medical-grade adhesive is similar to other products in HCPCS Level II code L8031.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8031 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8031 is \$430.74.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Amoena USA disagreed with CMS' preliminary determinations. The commenters stated that Amoena Adapt Air™ Contact prosthesis is distinguished from other products under HCPCS Level II code L8031 by its combination of adhesive functionality and adjustability and is not comparable to standard prefabricated silicone prostheses. Clinically, adhesive prostheses serve three subpopulations that cannot be adequately served by non-adhesive alternatives: for those at risk for lymphedema, where adhesive design shifts weight away from the shoulder strap; for those with radiation-altered chest wall contours, where standard prostheses fail to conform properly; and for those with active lifestyle, where pocketed prostheses tend to shift and reduce wear adherence. Given this functionality, the commenter proposed a new HCPCS Level II code with an initial allowable amount of \$625, representing approximately a 40 percent premium over the comparable baseline of approximately \$445 for HCPCS Level II code L8031. . The commenter stated that this pricing is supported by component cost differentials, wholesale and retail pricing data, and fitter labor considerations, with a gap-fill review recommended following one complete reporting cycle is not comparable to standard prefabricated silicone prostheses and payment should instead be gap-filled using verifiable commercial pricing. A commenter stated that the higher cost of these items is justified by unique features and by macroeconomic pressures such as silicone supply fluctuations, labor and mining costs, and geopolitical factors, which have driven production costs up approximately by 50 percent since year 2020.

Amoena USA further clarified that the price of roughly \$450 mentioned during the public meeting was a suggested retail price used for presentation purposes only and acknowledged that manufacturer suggested retail prices are not an appropriate basis for establishing Medicare payment amounts. Instead, the commenter requested gap-fill payment amount grounded in verifiable commercial pricing and documented cost information, reflecting the higher acquisition cost and market value of their product relative to standard silicone breast prostheses.

The commenter also clarified a prior statement from the public meeting. The intent was never to suggest CMS to re-price using Medicare claims or billing data, but rather that Amoena USA would submit updated verifiable supplier and commercial pricing after one full update cycle to allow CMS to confirm or adjust the amount.

The commenter stated that while Amoena Adapt Air™ Contact have historically been billed under HCPCS Level II code L8031 due to the absence of a better fitting code, this should not be interpreted as confirmation that this code accurately describes the technology and its cost. And that CMS' proposed preliminary determination would permanently fold these adjustable air-chamber devices into a code built for basic prefabricated forms. The commenter stated that HCPCS Level II code L8031 sets the wrong payment for these products. Further, the commenter said that they are not claiming that these products cannot be furnished at the current rate, but rather that the rate creates unsustainable margin pressure on suppliers.

Another commenter emphasized the uniqueness of Amoena USA products, noting that out of everything she has tried, these are the only ones that have met her expectations and left her fully satisfied.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to:

Revise existing HCPCS Level II code L8031, "Breast prosthesis, silicone or equal, with integral adhesive" to instead read "Breast prosthesis, silicone or equal, with integral adhesive, any type" to describe Amoena Adapt Air™ Contact.

CMS notes that various Amoena Adapt Air™ products featuring the air-chamber technology have historically been billed under HCPCS Level II code L8031. This billing history supports CMS' determination that the revised descriptor appropriately captures the product.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8031 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8031 is \$430.74.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Amoena Custom Adapt Air™ - HCP251224XANLD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Amoena Custom Adapt Air™.

Applicant's suggested language: LXXXX, “Breast prosthesis, external, custom-fabricated, silicone, with individually adjustable air-chamber back, designed from 3D anatomic scan, any type, each”

Summary of Applicant's Submission

Amoena USA submitted a request to establish a new HCPCS Level II code to identify Amoena Custom Adapt Air™. Amoena Custom Adapt Air™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Amoena Custom Adapt Air™ is an user specific external silicone breast prosthesis fabricated using 3D digital scanning to replicate an individual's exact postoperative chest wall anatomy, including irregular contours, scar patterns, and volume deficits; it also integrates an adjustable air-chamber back that allows individualized modification of projection and contour after fabrication. The prosthesis functions to replace absent breast tissue following mastectomy or breast surgery, providing precise anatomical symmetry and enabling ongoing adjustment to accommodate weight fluctuation, lymphedema-related swelling, or progressive changes in scar tissue.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code L8035, “Custom breast prosthesis, post mastectomy, molded to patient model” to instead read “Custom breast prosthesis, post mastectomy, molded to patient model, any type” to describe Amoena Custom Adapt Air™.

Amoena Custom Adapt Air™, a silicone, custom-fabricated breast prosthesis is similar to other products in HCPCS Level II code L8035.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8035 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8035 is \$4,505.38.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Amoena USA agreed with CMS' preliminary determinations. The commenter agreed that the revised HCPCS Level II code L8035 describes Amoena Custom Adapt Air™. The commenter added that adjustability alone does not warrant a new HCPCS Level II code, that descriptor expansion is a legitimate tool when functional differences are modest, and that coding decisions should be evidence-driven rather than innovation-driven.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to:

Revise existing HCPCS Level II code L8035, "Custom breast prosthesis, post mastectomy, molded to patient model" to instead read "Custom breast prosthesis, post mastectomy, molded to patient model, any type" to describe Amoena Custom Adapt Air™.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code L8035 apply to this product, if covered. The average 2026 fee schedule amount for HCPCS Level II code L8035 is \$4,505.38.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Veristra™ - HCP251230VLMD5

Topic/Issue

Request to establish a new HCPCS Level II code to identify Veristra™.

Applicant's suggested language: XXXXX, “Software-enabled dialysis access management system, including cannulation site mapping, puncture history tracking, hazard-zone designation, and access preservation decision support; per patient, per dialysis session”

Summary of Applicant's Submission

Health Data Works, Inc. submitted a request to establish a new HCPCS Level II code to describe Veristra™. Veristra™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is an FDA-registered, individual-specific clinical service used during routine outpatient hemodialysis treatment to support dialysis vascular access cannulation. Veristra™ enables objective, longitudinal visualization and quantification of dialysis access cannulation patterns across treatment sessions through treatment-integrated imaging and spatial analysis of cannulation site distribution, including identification of staff or clinician-designated avoidance zones related to access integrity. The function of the service is to inform real-time cannulation decisions during dialysis sessions, promote consistent and evidence-informed needle placement, and reduce access injury associated with repetitive or uneven cannulation during end-stage renal disease (ESRD) treatment. Again, Veristra™ is not a documentation, record-keeping, or administrative system, nor a general software subscription, rather, it represents a discrete, per-individual clinical service performed in conjunction with dialysis treatment that provides treatment-integrated visualization and quantitative assessment of cannulation patterns.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Veristra™. This item is intended for use with a dialysis machine, which is typically dialysis treatment for ESRD. For Medicare, when Veristra™ is used for the treatment of ESRD covered under the ESRD prospective payment system (PPS), this product would be considered included in the ESRD PPS bundled payment.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Dialysis items and services do not fall under any current DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination. CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Veristra™. This item is intended for use with a dialysis machine, which is typically dialysis treatment for ESRD. For Medicare, when Veristra™ is used for the treatment of ESRD covered under the ESRD PPS, this product would be considered included in the ESRD PPS bundled payment.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

MenHealth - HCP25122927P00

Topic/Issue

Request to establish a new HCPCS Level II code to identify MenHealth.

Applicant's suggested language: KXXXX, "Mobile uroflowmeter"

Summary of Applicant's Submission

BE Technologies submitted a request to establish a new HCPCS Level II code to identify MenHealth, a urinary flowmeter. MenHealth received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 27, 2014. This prescription-only device is used to evaluate lower urinary tract symptoms in male individuals. The MenHealth device provides real time urine flow measurements, such as flow curves and voided volume by using patented spectral analysis to analyze the sound of urine hitting toilet water and converts these sound spectra into quantifiable data such as flow curves with voiding parameters.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes MenHealth.

MenHealth is an integrated monitoring device that provides real time urine flow measurements, such as flow curves and voided volume. MenHealth is similar to other monitoring device products in HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9279 applies to the MenHealth urinary flowmeter.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9279 apply to this product. Items or services described by HCPCS Level II code A9279 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

BE Technologies disagreed with CMS' preliminary determinations. Specifically, the commenter stated that this product is diagnostic, not just monitoring, and so the existing HCPCS Level II code A9279 does not accurately describe this product. The HCPCS Level II code A9279 is a "catch-all" only, for generic monitoring. MenHealth performs a standardized, complex urological test (uroflowmetry). The commenter reiterated that the MenHealth product is a diagnostic uroflowmetry system, and not passive monitoring. MenHealth produces clinical diagnostic endpoints such as, maximum flow rate (Qmax), average flow rate, voided volume, and flow curve morphology.

The commenter further stated that Medicare already recognizes office-based uroflowmetry. Moreover, MenHealth performs the same clinical function in the home setting, such as, flow measurement, diagnostic interpretation, and clinical treatment support. These are all considered established urologic diagnostic measurements that use AI-powered sound analysis for urological diagnostics. The product listens to urine flow hitting the toilet water and converts sound into clinical grade uroflowmetry data, helping physicians detect, monitor, and evaluate lower urinary tract symptoms in male individuals.

The commenter requested for CMS to reconsider its preliminary HCPCS Level II coding determination and instead establish a new unique HCPCS Level II K code for MenHealth. The commenter also responded to a question about treatment, and reiterated that this product does not treat, it is a test, and only diagnostic in nature. They further explained that this product is like having lab tests or imaging done, which basically provides a tool which is diagnostic, and produces data pathways, which then help clinicians diagnose and make clinical decisions.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes MenHealth.

MenHealth is an integrated monitoring device that provides real time urine flow measurements, such as flow curves and voided volume. MenHealth is similar to other monitoring device products in HCPCS Level II code A9279 in that it collects and transmits physiological data to support health care practitioner decision-making. While the device captures urological measurements that may inform clinical decisions, the clinical interpretation is performed by the health care practitioner, not the device itself. This product does not treat a medical condition but instead monitors an individual's urinary health, allowing health care practitioners to make more informed clinical decision. The information collected by the device is not used to deliver immediate medical intervention to the individual utilizing the device.

Final Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

The MenHealth urine flow meter is used to measure and analyze urinary flow parameters for the evaluation of lower urinary tract symptoms (LUTS). Its primary function is diagnostic and monitoring in nature, as it collects data to assist clinicians in assessing a patient's condition. The device does not provide treatment for a disease or injury. Therefore, the device does not fall within a Medicare DMEPOS benefit category.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9279 apply to this product. Items or services described by HCPCS Level II code A9279 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Splashblocker® - HCP260102FQ98X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Splashblocker®.

Applicant's suggested language: XXXXX, “Portable, reusable engineering source control barrier, 100% medical-grade Tritan™, monolithic design; validated to reduce aerosolized medical waste particulates (PM 0.3) by 99.98% at point-of-origin. For use during cytotoxic, radiopharmaceutical, or infectious shedding cycles. Min. 3-year life”

Summary of Applicant's Submission

Splashblocker® Distribution Company, LLC submitted a request to establish a new HCPCS Level II code to identify Splashblocker®. Splashblocker® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Splashblocker® is a monolithic medical device injection-molded from medical-grade Eastman Tritan™ copolyester and engineered for a minimum three-year service life. The device functions as a high-performance, mobile engineering control that manages air displacement during the disposal of medical waste, providing a validated 99.98% reduction in aerosolized particulates at the point of origin. Its portable design allows oncology and infectious disease patients to maintain source-control compliance at any point of use within the home environment.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes Splashblocker®.

Splashblocker® acts as a physical barrier to intercept and capture toilet plume aerosols at the point of origin, preventing the environmental emission of hazardous drug metabolites and infectious pathogens during flushing. Like other items and services classified under HCPCS Level II code A9270, Splashblocker® does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. The Splashblocker® does not meet the following condition:

Is primarily and customarily used to serve a medical purpose - The Splashblocker® is used for safety, hygiene and to prevent infections. It is not used to treat an illness or injury or improve the function of a malformed body member.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

Splashblocker® Distribution Company, LLC and other commenters disagreed with CMS' published preliminary determinations. The commenter stated that Splashblocker® is primarily and customarily used to serve a medical purpose, particularly for immunocompromised users with cancer undergoing chemotherapy, who are at a high risk of a secondary illness. Therefore, Splashblocker® meets all five conditions required to be classified as DME. In CMS' preliminary HCPCS Level II coding determination, CMS appears to have gone beyond the regulatory definition of DME, which requires that an item be "primarily and customarily used to serve a medical purpose." The commenter noted that CMS has instead relied on the separate statutory concept of medical necessity, which requires that an item "treat an illness or injury," as a basis for denying the request. The commenter stated that preventative measures and treatment are not mutually exclusive. An item may be preventative in nature while still contributing to the treatment of an existing medical condition by preventing further complications or aggravation of the underlying illness. The commenter further stated that Splashblocker® serves a medical purpose by interrupting autoinoculation in immunocompromised users undergoing chemotherapy, thereby helping to prevent exposure to the user's own bacterial flora and reducing the risk of infection. The commenters referred to multiple articles, some of which were identified as having been published in the Journal of Occupational and Environmental Hygiene, the American Journal of Infection Control, and the American Journal of Nursing. The article published in the Journal of Occupational and Environmental Hygiene discussed how flushing uncovered toilets in hospitals has been shown to generate toilet plume aerosols that can carry

infectious pathogens and hazardous drugs used in cancer treatment. Within this study, 15 hospital centers spanning 9 states analyzed 145 toilets. The commenters noted that it was concluded that there was a median reduction in toilet plume aerosols of 99.98%. The article published in the American Journal of Infection Control discussed the impact of lid closure during toilet flushing and toilet bowl cleaning on viral contamination of surfaces in United States restrooms. The article also described how viral aerosols generated during toilet flushing may represent a potential route of pathogen transmission. A commenter explained that the 2024 American Journal of Nursing article showed evidence of infectious risks stemming from toilet plume aerosols from surface contamination and inhalation.

Multiple commenters compared the Splashblocker® to the Respirgard II, which is coded within HCPCS Level II code A7006, “Administration set, with small volume filtered pneumatic nebulizer,” as they both address the same hazardous drug risk but at a different point of the care cycle. They further stated that Respirgard II is a source control designed to contain hazardous drug aerosols during the inhalation and/or exhalation phase. While Splashblocker® is a source control designed to contain hazardous drug aerosols during the excretion phase. Another commenter stated that CMS has a long history of recognizing that devices modifying a hazardous environment to protect vulnerable tissue serve a primary medical purpose, including pressure reducing mattresses and negative pressure wound therapy.

CMS Final HCPCS Coding Determination

We appreciate the comments and clinical studies provided in response to CMS’ published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, “Non-covered item or service” describes Splashblocker®.

The Splashblocker® is not comparable to a nebulizer, such as Respirgard II. A nebulizer is a medical device that converts liquid medication into a fine mist (aerosol) so it can be inhaled directly into the lungs. It is commonly used to treat respiratory conditions such as asthma, chronic obstructive pulmonary disease, and other pulmonary conditions. Nebulizers deliver medication deep into the airways and lungs. Splashblocker® acts as a physical barrier to intercept and capture toilet plume aerosols at the point of origin, preventing the environmental emission of hazardous drug metabolites and infectious pathogens during flushing. Like other items and services classified under HCPCS Level II code A9270, Splashblocker® does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare.

We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

The Splashblocker® is an environmental control device used to control aerosols generated during toilet flushing to keep the air in the beneficiary's living space free of contaminants. As stated in section 110.1.B of chapter 15 of the Medicare Benefit Policy Manual, devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. Regarding the feedback about going beyond the definition of DME and relying on a separate provision of the statute in establishing the preliminary benefit category determination, this is an integral part of Medicare benefit policy analysis. Section 1862 of the Social Security Act (the Act) includes various mandates for excluding items and services from Medicare. As established in regulations at 42 CFR 414.240(b), the procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) meet the definition of DME start with CMS performing an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act. Section 1862(a)(1)(A) of the Act excludes items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. If an item is not used for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, it is excluded from Medicare coverage notwithstanding any other provision of title XVIII of the Social Security Act.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

RevoFit® Lamination Kit - HCP260102PP5Y4

Topic/Issue

Request to establish a new HCPCS Level II code to identify RevoFit® Lamination Kit for custom fabricated orthoses.

Applicant's suggested language: XXXXX, "Addition to lower extremity, inseparable, mechanically advantaged precision tension actuator-driven system with integrated circuit and channels that redistributes load through the orthotic structure, for custom fabricated orthoses"

Summary of Applicant's Submission

Click Medical submitted a request to establish a new HCPCS Level II code to identify RevoFit® Lamination Kit (RF) when integrated into custom fabricated lower limb offloading orthoses. RF is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). RF is a mechanically advantaged precision tension actuator-driven system integrated into and inseparable from custom fabricated orthoses. RF functions as an internal load redistribution mechanism distinct from its role in prostheses as a volume management system, and distinct from all other orthotic closure mechanisms. Deeper investigation with orthotic experts clarified RF's therapeutic benefits that focuses on how adjustable internal tension within the laminated structure influences internal load pathways. This effect equates to structural tension modulation within the laminate that results in load redistribution, which creates distinct mechanical effects on load redistribution, joint control, and orthotic performance during weightbearing.

CMS Preliminary HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle (prior application HCP241230DU444), CMS concluded that when added to a lower limb offloading orthosis, the RevoFit® Lamination Kit (RF) functioned similarly to a closure system (i.e., a strap) and that volume management does not apply to orthoses. The applicant revised its prior position and submitted this new application reflecting an updated rationale for coding consideration.

In its prior submission, the applicant described RF as incorporating a structural tension pathway that stabilizes limb-orthosis engagement and influences internal load transfer during weightbearing. In this application, however, the applicant presents RF as an integrated mechanical load redistribution system embedded within the laminated structure of a custom fabricated orthosis. The applicant has refined its submission to focus on RF's structural and biomechanical contribution to offloading and pain reduction.

Despite this revised articulation, CMS maintains that the item does not offer a function beyond force redistribution that is not already described by existing HCPCS Level II codes. The features cited by the applicant such as user-adjustable mechanical systems, circumferential pressure, and internal load redistribution are consistent with long-established lower-limb offloading orthoses, particularly patellar tendon-bearing type designs. Reframing the system as a force-redistribution mechanism does not establish a new mechanism of action or clinical function, as force

redistribution through compression and structural orthotic design is already well described within the existing coding framework.

Accordingly, CMS finds that existing HCPCS Level II code L2350, “Addition to lower extremity, prosthetic type, (bk) socket, molded to patient model, (used for ‘ptb’ ‘afo’ orthoses),” describes the RevoFit® Lamination Kit when used in custom fabricated orthoses.

CMS further determines that the inclusion of a BOA® dial-based system does not represent a distinct mechanical mechanism sufficient to establish a unique force redistribution function. The BOA® system serves as an alternative method of applying and maintaining tension, similar in purpose to traditional straps, lacing systems, or buckles, and does not independently generate or alter force distribution beyond what is achievable through established orthotic designs.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code L2350 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code L2350 is \$1,175.80.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Click Medical, LLC, and other commenters disagreed, with CMS’ preliminary determinations. The commenters stated that current HCPCS Level II code L2350, “Addition to lower extremity, prosthetic type, (bk) socket, molded to patient model, (used for ‘ptb’ ‘afo’ orthoses)” does not adequately describe the features of the RF. Commenters stated that RF is currently being billed with existing HCPCS Level II code L2999, “Lower extremity orthoses, not otherwise specified,” but they requested that CMS support broader access and reimbursement by either establishing a unique orthotic HCPCS Level II code, or crosswalk RF to the existing prosthetic HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system (with or without lamination kit).” The commenters further stated that existing orthotic addition HCPCS Level II codes do not adequately describe an integrated mechanical load redistribution system like RF and they urged CMS to recognize the RF as a distinct therapeutic intervention by establishing a new HCPCS Level II code.

Commenters explained that the applicant moved from a “volume management” argument in 2024 to a “tension-based load redistribution” argument in 2025 in response to CMS feedback but

reiterated that the underlying technology of RF did not change. Commenters stated that in efforts to align prosthetic and orthotic use, the applicant described RF in 2024 as a volume-management system allowing precise contact as limb volume fluctuates; but CMS later concluded that “volume management” was not a recognized orthotic principle. Commenters further explained that based on CMS’ feedback, the applicant later reframed its submission around adjustable internal tension improving device-limb contact and optimizing load transfer; and CMS recognized this function as already described by HCPCS Level II code L2350. The commenters noted that while both “volume management” and “tension-based load redistribution” are concurrent effects of the same system, many clinicians do not universally agree on the terminology, which makes it difficult to describe the integrated mechanical system of RF within the existing HCPCS Level II code set. While the commenters appreciated CMS’ 2025 validation that RF performs a distinct and meaningful function in custom offloading orthoses, they disagree that an existing HCPCS Level II code adequately describes this function.

Commenters noted that RF is an integrated tensioning system within orthotic devices, offering internal adjustment and accommodating anatomical changes, unlike traditional Patellar Tendon-Bearing (PTB) braces or Ankle-Foot Orthoses (AFOs), which use external Velcro straps prone to loosening and limited adjustability. Commenters emphasized that the RF’s mechanical tension pathways, dial system, and dynamic load distribution improve limb suspension, maintain pressure during walking, offload distal joints, enhance patient independence, adherence, and wear time. They stated that its benefits can also apply to custom devices like articulated AFOs with pre-tibial shells. The commenters also cited clinical studies that show reduced pain, better functional scores, durable results, and prevention of amputations. Commenters emphasized that RF’s tensioning system provides a therapeutic function not achieved by standard closure systems.

The commenters explained that RF is distinct from consumer closure systems like the BOA® Closure System, using proprietary components for daily orthotic and prosthetic use and instead includes a stainless-steel spool, metal gear train, Spectra lace, and plastic housing. They highlighted that RF can be incorporated into multiple orthotic designs, is not limited to PTB trim lines or patellar tendon contact, accommodates anatomical changes, allows easier donning and doffing, and is especially helpful for patients with weak hand function, stroke, or spinal cord injury. The commenters also explained that BOA® Technology Inc. manufactures the BOA® Closure System as a consumer-grade product for footwear and lightweight orthoses, with plastic reels for low-force applications, while Click Medical, LLC produces the Click Reel, which is a metal-component reel engineered to sustain tension forces required for clinical offloading and intended to last the life of the prosthetic and orthotic device. Commenters clarified that since 2022, BOA® components are no longer present in the RF, and they emphasized that the Click Reel is not merely an alternative fastener, but a 7:1 mechanical-advantage tension actuator integrated into the laminate as part of an inseparable internal circuit.

Some commenters highlighted their experiences using the devices as clinical professionals and individuals with osteosarcoma, spinal cord injuries and limb salvage procedures. The commenters described challenges with using traditional orthoses, including poor fit, a lack of adjustability, discomfort, instability, chronic pain, and limited mobility leading to missed opportunities for daily activity and employment. The commenters reported that the adjustable orthotic technology with RF offers the ability to self-adjust fit throughout the day resulting in

greater comfort, improved support, reduced complications, longer device usage, increased activity, strength, endurance, balance, confidence, reduced falls, continued rehabilitation progress, and in some cases, avoidance of amputation.

CMS Final HCPCS Coding Determination

We appreciate the comments submitted in response to CMS' published preliminary determinations. After reviewing the application and carefully considering the information provided by commenters, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code L2350, "Addition to lower extremity, prosthetic type, (bk) socket, molded to patient model, (used for 'ptb' 'afo' orthoses)," to describe the RevoFit® Lamination Kit when used in custom fabricated orthoses.

CMS recognizes that the RevoFit® Lamination Kit is intended to be used in conjunction with custom-fabricated carbon-fiber AFOs and not as a stand-alone orthotic component. Accordingly, CMS notes that existing codes, such as HCPCS Level II code L2755, "Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only," may also be applicable in describing the carbon-fiber composite construction of the finished orthosis that incorporates both carbon-fiber construction and the RevoFit® Lamination Kit.

CMS acknowledges that the RevoFit® Lamination Kit for lower-limb prostheses, currently described by HCPCS code L5783, may assist in maintaining fit and accommodating changes associated with weight gain or weight loss, as the applicant suggests. However, the clinical significance of such changes differs between orthotic and prosthetic devices. Although the RevoFit® Lamination Kit incorporates an integrated tensioning mechanism, its use alone does not constitute a new clinical function. Orthoses have long incorporated adjustable features that accommodate changes in limb volume, soft tissue contours, and body habits while maintaining fit and function. The ability to maintain internal tension and redistribute forces during gait is a function of the adjustment mechanism itself and does not establish that an orthosis incorporating the RevoFit® Lamination Kit is fundamentally different from other orthotic designs that permit fit modification.

CMS recognizes that the RevoFit® Lamination Kit may provide a more convenient or mechanically advantageous method of adjusting fit. However, this does not establish a distinct clinical function. Traditional PTB orthoses and other custom-fabricated orthotic designs have historically achieved similar clinical objectives through strap adjustments, padding modifications, closure systems, trimline design, and other fitting techniques. While the RevoFit® Lamination Kit may represent a different method of achieving these objectives, the distinction lies primarily in the method of adjustment rather than in the underlying clinical goal of maintaining fit, load distribution, alignment, and functional performance.

CMS does not dispute the clinical studies cited by commenters or the reported outcomes associated with orthoses incorporating the RevoFit® Lamination Kit. Commenters assert that the RevoFit® Lamination Kit provides therapeutic functions not achieved by standard closure

systems. CMS notes, however, that other orthotic designs utilize alternative structural configurations, load-sharing mechanisms, anterior shell designs, force-transfer principles, and custom-fitting techniques to achieve similar clinical objectives, including limb offloading, force redistribution, improved control, enhanced suspension, and accommodation of anatomical changes. While the RevoFit® Lamination Kit may provide one means of achieving these outcomes, the available information does not demonstrate that these functions are exclusive to orthoses incorporating the RevoFit® Lamination Kit.

The applicant describes the RevoFit® Lamination Kit as providing an adjustable internal load-redistribution interface. CMS recognizes that the system may facilitate fit adjustment and tension management. However, PTB-style AFOs and other custom-fabricated orthoses have historically incorporated design features intended to redistribute forces, improve limb control, and enhance fit. A PTB-style AFO does not fully suspend or de-weight the foot. Rather, it functions by controlling tibial motion, improving proximal stability, and redistributing forces through the orthotic structure. Tightening occurs around the PTB region and surrounding limb segments depending upon the fit and fabrication of the orthosis. In this respect, the biomechanical objectives described by the applicant are not entirely dissimilar from those achieved by other custom-fabricated PTB-style orthotic designs.

The applicant further stated that the dial should be viewed as a tension actuator rather than merely a fastener and notes that it operates through an internal tension pathway at approximately a 7:1 mechanical ratio. CMS acknowledges that the dial mechanism performs an adjustment function. However, the system also serves as a closure mechanism because the orthosis must be opened and closed through the dial-based interface. The fact that the system performs tensioning functions does not negate its role as a closure system, nor does the fact that it functions as a closure mechanism establish that it performs a distinct orthotic function. Similarly, the applicant's assertion that the RevoFit® Lamination Kit provides individual-adjustable internal preload while preserving alignment across adjustments does not demonstrate a unique therapeutic function. Although the technology may improve convenience and usability for some beneficiaries, orthoses have historically incorporated straps, pads, closures, and other fitting mechanisms that permit adjustment of fit and accommodation of anatomical changes. The applicant's submission demonstrates a different method of achieving these objectives but does not establish that the underlying clinical goals are unique to the technology.

CMS also notes that dial-based closure systems are currently utilized in connection with other orthotic products. As a result, it is not entirely clear how the RevoFit® Lamination Kit differs, from a functional perspective, from other dial-based tensioning and closure systems currently available. The record suggests that the RevoFit® Lamination Kit may represent a more robust or specialized implementation of such technology; however, the available information does not demonstrate that it performs a distinct orthotic function that is not otherwise addressed through existing technologies. CMS further notes that dial-based adjustment mechanisms have become increasingly common across a variety of orthotic applications. The existence of a different adjustment mechanism itself does not establish that a distinct HCPCS Level II code is warranted.

Finally, CMS notes that the applicant suggests that meaningful offloading can be achieved through both PTB-style and non-PTB-style carbon-fiber AFO designs. If offloading can be

achieved through orthoses with trimlines shorter than those typically associated with PTB-style designs, existing coding pathways may already be available. In particular, CMS notes that HCPCS Level II code L2330, "Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only," describes an orthosis molded to a model of the patient and may be relevant in certain circumstances. Similar coding considerations have historically arisen in connection with Arizona-type AFOs and other custom-fabricated orthoses designed to redistribute forces, provide stability, or achieve partial de-weighting of the lower extremity.

Final Medicare Benefit Category Determination

Leg Brace.

Final Medicare Payment Determination

The applicant argues that HCPCS Level II code L5783 reimburses an adjustable internal socket interface in a prosthesis and that the requested orthotic addition would reimburse an adjustable internal load-redistribution interface in a custom-fabricated AFO. CMS acknowledges this argument. However, CMS notes that prosthetic socket volume management and load distribution are fundamental requirements for successful prosthetic use. The applicant has not demonstrated that the orthotic application under consideration presents an equivalent clinical need or that the functions performed by the RevoFit® Lamination Kit are analogous to those performed by the prosthetic component described by HCPCS Level II code L5783.

The payment rules and pricing associated with the existing HCPCS Level II code L2350 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code L2350 is \$1,175.80.

As noted, since this item is used as part of an AFO that incorporates carbon fiber construction, L2755 may also be billed where appropriate. The current average 2026 fee schedule amount for HCPCS Level II code L2755 is \$160.04.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

DermiSphere™ hDRT - HCP260102TL8N8

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermiSphere™ hDRT.

Applicant's suggested language: XXXXX, “DermiSphere hDRT, per square centimeter”

Summary of Applicant's Submission

Fesarius Therapeutics Inc. submitted a request to establish a new HCPCS Level II code to identify DermiSphere™ hDRT. DermiSphere™ hDRT received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on January 6, 2025.

DermiSphere™ hDRT is an advanced wound dressing comprised of crosslinked bovine collagen microspheres embedded in bovine collagen hydrogel matrix. This composite biodegradable wound dressing provides a scaffold for native tissue cellular invasion and capillary growth. DermiSphere™ hDRT is a wound dressing indicated for the management of wounds including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post Mohs surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns and skin tears) and draining wounds. This device is intended for one-time use. A single piece of DermiSphere™ hDRT is packaged between two protective polyester sheets and packed in a peelable tray, which is packed inside a peelable laminated foil pouch.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Dermisphere hDRT, per square centimeter” to describe Dermisphere™ hDRT.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is revising its preliminary determination to:

Establish a new HCPCS Level II code A2046, “Dermisphere hDRT, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Dermisphere™ hDRT.

Fibrillar Collagen Wound Dressing - HCP251223WGYKB

Topic/Issue

Request to establish a new HCPCS Level II code to identify Fibrillar Collagen Wound Dressing.

Applicant's suggested language: XXXXX, "HELIOGEN® Fibrillar Collagen Matrix per mg"

Summary of Applicant's Submission

MIMEDX Inc. submitted a request to establish a new HCPCS Level II code to identify Fibrillar Collagen Wound Dressing. Fibrillar Collagen Wound Dressing received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 31, 2022. Fibrillar Collagen Wound Dressing is a single-use, advanced fibrillar collagen matrix intended for the management of moderately to heavily exudated wounds and to control minor bleeding. Fibrillar Collagen Wound Dressing is indicated for the management of exuding wounds, including diabetic ulcers, venous stasis ulcers, pressure ulcers, acute wounds such as trauma and surgical wounds, and partial-thickness burns. The matrix contains a triple helical structure, comprised of type I and type III bovine collagen. Fibrillar Collagen Wound Dressing is designed to absorb exudate and has intrinsic hemostatic properties to control minor bleeding and protect the wound bed and delicate new tissue. Fibrillar Collagen Wound Dressing is an absorbent extracellular matrix that closely resembles the body's native collagen through a manufacturing process designed to preserve the collagen's natural, triple helix structure. Fibrillar Collagen Wound Dressing can be applied as a powder, a paste, or putty like consistency, or a slurry mixture based on clinical need. Fibrillar Collagen Wound Dressing delivers a biocompatible collagen matrix to serve as a scaffold in support of tissue regeneration and achieves both biocompatibility and biodegradation, generating low inflammatory activation to allow the product to persist long enough for reparative processes to commence. The product is available in 500 mg, 1000 mg, and 2000 mg. Fibrillar Collagen Wound Dressing is applied ¼ inch thick to the wound surface, and the wound is not wrapped tightly to allow for expansion of the fibrillar particles. Additionally, Fibrillar Collagen Wound Dressing can be hydrated with sterile saline to form a paste to aid in the application, where the location or geometry of the wound may make it difficult to apply the dry device. To make a paste, remove the lid of the jar provided or dispense Fibrillar Collagen Wound Dressing into a separate sterile container. Slowly add sterile saline until the desired consistency is obtained. The wound would then be covered with an absorbent dressing. Fibrillar Collagen Wound Dressing is packaged in an outer carton with appropriate labeling. Inside that carton is a thermoformed non-sterile tray which includes a sealed Tyvek®. Within the tray is a sealed vial containing the sterile product. Fibrillar Collagen Wound Dressing should be stored at room temperature (15°C/59°F to 30°C/86°F). Avoid excessive heat and humidity.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Fibrillar collagen wound dressing, per milligram" to describe Fibrillar Collagen Wound Dressing.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule Final Rule, Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

MIMEDX Inc. agreed with CMS' preliminary determination for the establishment of a new HCPCS Level II code to describe Fibrillar Collagen Wound Dressing.

CMS Final HCPCS Coding Determination

We appreciate the comment provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code A2050, "Fibrillar collagen wound dressing, per milligram" to describe Fibrillar Collagen Wound Dressing.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule Final Rule, Medicare payment for this product will be determined by the Medicare Administrative Contractors.

CAVEO - HCP260102Y53F7

Topic/Issue

Request to establish a new HCPCS Level II code to identify CAVEO.

Applicant's suggested language: XXXXX, "Fistula cannulation set for hemodialysis with passive dislodgement protection for venous, each"

Summary of Applicant's Submission

JMS North America Corporation submitted a request to establish a new HCPCS Level II code to identify CAVEO. CAVEO received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 15, 2025. CAVEO is an arteriovenous (AV) fistula needle set used in hemodialysis which passively prevents major blood loss in the event of a venous needle dislodgement (VND), with an anti-needlestick safety feature. The CAVEO is intended to protect individuals from the risks associated with the VND. It contains an integrated stainless steel torsion spring mechanism and bottom footplate that provides an open blood/fluid path when the AV fistula set is fully cannulated into the access site. When the venous needle becomes completely dislodged from the individual's arm, this mechanism enables the footplate to open and partially occlude the blood path, generating an increased venous line pressure high enough to trigger automatic alarm and halt further blood pumping of the hemodialysis machine. In vitro testing supports that this feature triggers the hemodialysis machine to alarm and shut off. Again, based on bench testing results, this should significantly reduce individual blood loss in the event of a complete VND. The CAVEO has a pre-attached anti-stick needle guard for the prevention of needlestick injury at the time of needle withdraw after completion of a hemodialysis procedure. The CAVEO device contains three specific novel components that enable the VND detection and machine shut-off functionality. It includes an underlying footplate, designed to lightly rest against the skin during cannulation or interrupt the blood flow path during VND, a spring which provides the energy for VND detection and blood flow occlusion, and an internal core with a flexible membrane, which enables the footplate to occlude the blood flow during VND. The existing HCPCS Level II code A4730 does not adequately describe this item or service, as it represents a fistula cannulation set for hemodialysis, but does not account for the passive needle dislodgement safety feature described here.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify CAVEO. This item is intended for use with a dialysis machine, which is typically dialysis treatment for end-stage renal disease (ESRD). For Medicare, when CAVEO is used for the treatment of ESRD covered under the ESRD prospective payment system (PPS), this product would be considered included in the ESRD PPS bundled payment.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Dialysis items and services do not fall under any current DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

JMS North America Corporation disagreed with CMS' preliminary determinations. The commenter then stated that CAVEO includes a vascular access component, not just a routine vascular access supply. CAVEO's primary function is circuit-level safety intervention. The commenter also stated that the key distinction is that unlike standard vascular access devices, which simply enable blood flow, CAVEO actively responds to catastrophic venous dislodgement by mechanically inducing a partial occlusion, directly altering extracorporeal circuit conditions, resulting in immediate treatment termination. It is not detection, and/or monitoring. CAVEO mechanically enforces a circuit condition during a venous needle dislodgement event that necessitates immediate dialysis machine shutdown, without relying on machine detection to identify the dislodgement.

The commenter further stated that the current ESRD PPS bundled care approaches to venous needle dislodgement rely on a detection-based safety model, including, access securement (taping), staff monitoring, and machine-based safety systems that detect and respond to changes in pressure, flow, or other circuit parameters. CAVEO intervenes at the point of dislodgement and directly alters extracorporeal circuit conditions at that moment. As such, the commenter further explained that CAVEO is not reflected in the ESRD PPS base rate, and introduces a fundamentally different approach to managing a serious dialysis risk.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination.

CAVEO is an arteriovenous fistula needle used in individuals with ESRD, who require regular, scheduled hemodialysis treatments. CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify CAVEO. This item is intended for use with a dialysis machine, which is typically dialysis treatment for ESRD. For Medicare, when CAVEO is used for the treatment of ESRD covered under the ESRD PPS, this product would be considered included in the ESRD PPS bundled payment.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Expandable Rolling Bathtub- HCP250723QJMX

Topic/Issue

Request to establish a new HCPCS Level II code to identify Expandable Rolling Bathtub.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Morgan A H Medical submitted a request to establish a new HCPCS Level II code to identify Expandable Rolling Bathtub. Expandable Rolling Bathtub is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Morgan A H Medical Expandable Rolling Bathtub is a durable, portable bathing system designed for individuals with limited mobility who are unable to safely access a standard bathtub or shower. The Expandable Rolling Bathtub primary function is to provide a safe, hygienic, and accessible bathing solution for homebound or mobility-impaired individuals by enabling caregivers to bathe patients at the bedside or in alternative care settings. The bathtub operates through manual positioning and water transfer from an external water source, allowing for safe bathing without requiring patient transfer to a bathroom.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes Expandable Rolling Bathtub.

The Expandable Rolling Bathtub is a portable bathing system designed for individuals with limited mobility who are unable to safely access a standard bathtub or shower. Like other items and services classified under HCPCS Level II code A9270, Expandable Rolling Bathtub does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. An expandable rolling bathtub does not meet the following condition:

Is primarily and customarily used to serve a medical purpose - The Expandable Rolling Bathtub is used for safety, hygiene and to prevent infections. It is not used to treat an illness or injury or improve the function of a malformed body member.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, "Non-covered item or service" to describe Expandable Rolling Bathtub.

The Expandable Rolling Bathtub is a portable bathing system designed for individuals with limited mobility who are unable to safely access a standard bathtub or shower. Like other items and services classified under HCPCS Level II code A9270, Expandable Rolling Bathtub does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The Expandable Rolling Bathtub is not primarily used to serve a medical purpose. The item is used for safety, hygiene and to prevent infections. It is not used to treat an illness or injury or improve the function of a malformed body member.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Halo Safety Wing - HCP250924CN7H4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Halo Safety Wing.

Applicant's suggested language: XXXXX, “A bed-mounted safety device designed to prevent bed entrapment for individuals in care, with mobility limitations, cognitive impairment or who are at increased risk of rolling or falling from bed. Accessory is non-powered, detachable, not an integrated operational mechanical part of hospital bed”

Summary of Applicant's Submission

Halo Mobility Solutions LLC submitted a request to establish a new HCPCS Level II code to identify the Halo Safety Wing. The Halo Safety Wing is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Halo Safety Wing is an advanced safety accessory designed for individuals who require bed-related safety intervention but are not adequately protected by traditional bed rails or foam wedges. It directly addresses four of the most dangerous entrapment zones, as defined in the FDA’s guidance on hospital bed safety: zone 1 (within the rail), zone 2 (under the rail), zone 3 (between rail and mattress), and zone 4 (under the rail at the ends). These zones are particularly hazardous for individuals with dementia, Parkinson’s disease, or muscle weakness. Entrapment in these areas can result in fractures, skin trauma, or even asphyxiation.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0700, “Safety equipment, device or accessory, any type” describes Halo Safety Wing.

The Halo Safety Wing is an adjustable bed mobility vertical mounting bar designed to help prevent entrapment hazards. The Halo Safety Wing is similar to other products in HCPCS Level II code E0700.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code E0700 apply to the HALO Safety Wing.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code E0700 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

Halo Mobility Solutions LLC disagreed with CMS' published preliminary determinations. The commenter stated that the Halo Safety Wing represents a new category of bedside mobility technology that combines entrapment and fall prevention, user-directed mobility, and independent transfer assistance within a single device. Unlike traditional bed rails, these devices are designed to promote safe movement, maintain user strength and independence, reduce caregiver burden, and uniquely address identified entrapment zones. The commenter believes that establishing a distinct HCPCS Level II code is necessary to ensure appropriate therapy and equipment selection, as well as improved user outcomes.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type" to describe Halo Safety Wing.

The Halo Safety Wing is an adjustable bed mobility vertical mounting bar designed to help prevent entrapment hazards. Its intended use is consistent with HCPCS Level II code E0700, as it serves as a safety device for fall and entrapment prevention. The device is similar in function and purpose to other products classified under HCPCS Level II code E0700.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code E0700 apply to the HALO Safety Wing.

Final Medicare Payment Determination

Items or services described by HCPCS Level II code E0700 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

ATMOS C051 - HCP251007KCNJC

Topic/Issue

Request to revise existing HCPCS Level II code A7048, “Vacuum drainage collection unit and tubing kit, including all supplies needed for collection unit change, for use with implanted catheter, each”, to describe ATMOS C051.

Applicant's suggested language: A7048, “New technology recently FDA-cleared for home use, which reduces length of stay for patients with persistent air leaks while having remote monitoring capabilities to facilitate a hospital at home program”

Summary of Applicant's Submission

ATMOS INC. submitted a request to revise existing HCPCS Level II code A7048 to describe ATMOS C051. ATMOS C051 is a class II device which received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on March 7, 2025. ATMOS C051 is a digital drainage system monitor and display of air leaks, with a 24-hour graph of air leak trends, and 12 days of recording, which better protects patients at home. This device replaces the current analog device drains which use subjective bubble intensity and duration to make clinical decisions of when to remove a chest tube. The current analog devices also have no recording abilities, and no automatic warnings.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes ATMOS C051.

The ATMOS C051 is a drainage system that monitors and records to assist the physician in making treatment decisions for the individual. Like other items and services classified under HCPCS Level II code A9270, ATMOS C051 does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

In the application, the ATMOS C051 is described as a digital lung drainage device as part of a hospital at home program in order to reduce the individual’s length of stay in the hospital following lung resection surgery. It is our understanding that this device had only been previously available in the inpatient hospital setting that includes physician and nursing services to make device setting changes, change the canisters and address the device’s warning messages. However, the applicant explained that with the ATMOS C051 device that is intended for home

use, some hospitals include hospital at home programs that provide the services of paramedics to visit individuals on a daily basis and to make any necessary changes to the device according to a physician's orders. Additionally, the applicant stated that individuals are provided with training via a home use guide, QR codes to videos, and the ability to contact the clinical team who have been provided with a troubleshooting decision tree to triage any warning messages.

The Medicare program does not include a hospital at home program with regard to the DME benefit category. Once the supplier provides initial training to the beneficiary or beneficiary's caregiver on how to operate a covered device, the beneficiary or the beneficiary's caregiver must be able to use the equipment independently without on-going involvement from a clinician. If the patient has a problem with the ATMOS C051 device, the individual will have to follow up with the physician or go to a hospital's emergency room for help. The clinical support needed for use of this device exceeds the parameters of the DME benefit category. We do not question the effectiveness of the ATMOS C051 device, but we do not believe this device is appropriate for use in the home by the beneficiary or caregiver since clinical services by paramedics, physicians, and hospital staff are necessary for home use of the device. In addition, monitoring and recording functions of this item assists the physician in making treatment decisions of when to remove the chest tube. This functionality/utility and service falls outside the scope of the DME benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

ATMOS INC. disagreed with CMS' preliminary determinations. The commenter stated that the ATMOS C051 is intended for independent home use by a trained beneficiary or caregiver following standard discharge education, consistent with other DME devices. The commenter further stated that the device does not require ongoing clinical involvement for day-to-day operation, and that any participation by hospitals in transitional or hospital-at-home programs reflects care delivery choices rather than a functional requirement of the device itself. The commenter explained that this is not a clinical service platform, and it is not reliant on continuous clinician interaction. It does not introduce new clinical service requirements that generate data for later clinical review, but the device itself is intended for use at home following discharge.

The commenter also stated that the monitoring and recording functions of the ATMOS C051 record objective air leak and vacuum data to support informed clinical decision-making, but do not constitute clinical services. The commenter noted that many covered DME items incorporate

similar data recording features without being classified as clinical services, and that the presence of such features should not preclude consideration of the ATMOS C051 under a DME-aligned coding framework.

Regarding the furnishing model, the commenter explained that the ATMOS C051 consists of a reusable capital equipment component with an expected useful life of approximately five to seven years, along with single-use disposable canisters and tubing furnished per patient episode. The commenter stated that this capital-plus-consumables structure is consistent with established DME categories and that classification under HCPCS Level II code A9270 does not reflect the reusable nature of the equipment or support consistent claims adjudication. If the individual cannot be trained to change the cannister, or they are having problems with dexterity, or they do not have a caregiver to help them, these individuals are excluded from this use-at-home care outpatient program, therefore not everyone is eligible for home care.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination:

Existing HCPCS Level II code A9270, "Non-covered item or service" describes ATMOS C051.

CMS notes that the ATMOS C051 is described as a digital thoracic drainage system used in connection with transitional or hospital-at-home programs to support recovery following lung resection surgery and to reduce inpatient length of stay. The ATMOS C051 monitors and records to assist the physician in making treatment decisions for the individual. Like other items and services classified under HCPCS Level II code A9270, ATMOS C051 does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No determination.

After reviewing the HCPCS Level II application, the HCPCS Level II public meeting presentation, and the post public meeting comment, we continue to have questions regarding whether there are situations when the patient can independently use the ATMOS C051 device in the home setting and whether the main purpose of the device is to provide suction/treatment in the home as opposed to monitoring of the patient by the physician. We will continue to review this item and address these issues at a future public meeting. In the meantime, decisions regarding coverage and payment for any claims submitted for this item will be made by the DME MACs.

Final Medicare Payment Determination

No determination.

Gradient Compression Glove - HCP260102UYFD8

Topic/Issue

Request to revise the national payment amount for HCPCS Level II code A6581, “Gradient compression glove, each”.

Summary of Applicant's Submission

U.S. Medical Compression Alliance (USMCA) submitted a request to revise the national payment amount for HCPCS Level II code A6581, “Gradient compression glove, each.” This HCPCS Level II code was established with a national payment amount of \$69, which is artificially low and does not reflect the actual market cost of medical grade compression gloves. As currently priced, the national payment amount fails to cover the cost of goods for medical grade products, distribution, assessment and fitting support, and the insurance-related administrative costs required to ensure safe and effective access to these products. The result is a payment amount that undermines supplier participation and directly threatens beneficiary access. USMCA conducted additional research to better understand what data sources may have informed the original pricing determination and whether those sources accurately represent the medical grade compression glove market. Despite the prevalence of lymphedema, utilization of gradient compression gloves under Medicare and Medicaid is low, indicating a systemic access problem rather than limited clinical need. Medicare fee-for-service enrollment data shows approximately 33.8 million beneficiaries, yet Medicare 2024 data reflects only 3,666 claims for HCPCS Level II code A6581, representing a negligible fraction of the eligible population. Similarly, 2022 and 2023 Medicaid utilization for HCPCS Level II code S8427 ranged from just 0.002 percent to 0.05 percent of the covered population, levels that are inconsistent with epidemiologic estimates and standard treatment patterns for lymphedema, particularly among breast cancer survivors. This underutilization strongly suggests that current inadequate payment amount(s) are suppressing access by discouraging supplier participation and limiting beneficiary availability.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment amount for HCPCS Level II code A6581 was set as 120 percent of the average of Medicaid state plan fee schedule amounts in accordance with regulations at 42 CFR § 414.1650 and guidance provided under section 1834(z) of the Social Security Act. We have not identified any errors in the application of this methodology; therefore, we are unable to make any modification to the payment amount for HCPCS Level II code A6581.

Since the inception of the Medicare Part B benefit for lymphedema compression treatment items in 2024, we have included lymphedema treatment items in our frequent and ongoing monitoring of DMEPOS claims and beneficiary health outcomes data. As of December 31, 2025, claims data show that over 130,000 Medicare beneficiaries have received lymphedema compression

treatment items. Of these beneficiaries, 6,372 have received gradient compression gloves classified under HCPCS Level II code A6581, with an assignment rate (accepting the Medicare payment as payment in full) of 94.3 percent. With 4.9 percent of beneficiaries who have received a lymphedema compression treatment item having received an item under HCPCS Level II code A6581, this code is among the top ten of the lymphedema compression treatment items benefit.

Summary of Public Feedback

Commenters expressed understanding that the fee schedule amount was set in accordance with the regulations but felt that the resulting fee schedule amounts are not adequate and do not reflect the costs of fabricating and supplying gradient compression gloves. Commenters believe that utilization data alone is not an adequate measure of whether beneficiaries are suffering difficulties accessing lymphedema compression treatment items classified in HCPCS Level II code A6581 and encouraged CMS to evaluate utilization trends together with prevalence statistics to determine whether the fee schedule amounts are adequate for gradient compression gloves. Commenters invited CMS to enlist their help in compiling whatever additional data elements may assist in analyzing whether the payment amount for this code is adequate or not.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

We appreciate the concerns noted by the commenters. The public meeting process is used to obtain public consultation on preliminary coding determinations and DMEPOS benefit category and payment determinations. Broader discussions about whether payment amounts established in accordance with standard Medicare payment rules are reasonable is beyond the scope of this process.

UrgoK2 Lite (Ankle Circumference of 9 3/4"- 12 1/2") - HCP2512315R8FJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify UrgoK2 Lite for a lower limb with an ankle circumference of 9 3/4"- 12 1/2".

Applicant's suggested language: AXXXX, "Dual compression lymphedema bandage system (both short and long stretch therapy) providing 20 mmHg compression to a lower limb with an ankle circumference of 25-32 cm (9 3/4"- 12 1/2")"

Summary of Applicant's Submission

URGO Medical submitted a request to establish a new HCPCS Level II code to identify UrgoK2 Lite providing moderate compression for a lower limb with an ankle circumference of 25-32 cm (9 3/4"- 12 1/2"). UrgoK2 Lite is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is a dual compression system, composed of short stretch and a long stretch bandages. UrgoK2 Lite is indicated for treatment of adults with lower limb lymphedema where moderate compression is recommended. Its exclusive PresSure System with pressure spot indicators on both bandages, aids application of recommended therapeutic pressure (20 mmHg) at the correct stretch and correct overlap. UrgoK2 Lite is a two-layer, multi-component compression system designed to deliver continuous, consistent, and comfortable compression therapy to individuals with lower extremity lymphedema. UrgoK2 Lite dual compression system ensures continuous 24/7 compression regardless of an individual's activity level. KTECH Lite Layer 1 is a short-stretch non-elastic bandage which provides compression, protection, and absorbency. This short-stretch bandage has moderate working pressure when an individual is walking, and delivers 80 percent of the prescribed therapeutic compression. KPress Layer 2 is a cohesive long-stretch elastic bandage which has high resting pressure when an individual is at rest and provides the additional compression necessary to achieve the prescribed therapeutic compression. Because UrgoK2 Lite is more permeable to air and much thinner than most lymphedema compression bandages, users experience better breathability and mobility for long-term wear.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" describe UrgoK2 Lite for a lower limb with an ankle circumference of 9 3/4"- 12 1/2". While this two-layer compression system is indicated for treatment of venous stasis ulcers and venous edema, it also is used for lymphedema treatment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 8 yards of short stretch bandaging and 12 yards of long stretch bandaging, the total Medicare payment amount would be $8 \times \$1.70 + 12 \times \$1.55 = \$32.20$.

Pricing Indicator = 40

Summary of Public Feedback

URGO Medical disagreed with CMS' preliminary determinations. They stated that traditional compression bandages are not calibrated to work together, making it challenging for lymphedema professionals and users to consistently achieve the required 20 - 40 mmHg of therapeutic compression across all activity levels (walking, sitting, sleeping).

Instead, the UrgoK2 dual compression systems address this gap through four engineered features: calibrated compression where short and long stretch components are precisely calibrated to maintain therapeutic compression in all users' positions; interlocking layers where bandage layers form a scaffold-like structure that prevents slipping or migration; PresSure System indicators where visual spot indicators eliminate guesswork, ensuring correct stretch and compression levels, and absorbent & breathable fabric where the first layer manages lymphorrhea and breathable second layer improves users' comfort and compliance, enabling 24/7 wear.

The commenter stated that when this product is used for venous leg ulcers, each layer of the UrgoK2 system is assigned the same HCPCS Level II code A6452, and the 2026 Total Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) allowable rate for UrgoK2 is \$120.96 and \$163.80 based on an ankle circumference. UrgoK2 Lite is assigned HCPCS Level II code A6449 for one layer and A6452 for another layer, and the 2026 total DMEPOS allowable rate for UrgoK2 Lite is \$82.02 and \$116.60 based on an ankle circumference. URGO Medical does not sell their products directly, they use distributors. The commenters added that the UrgoK2 and UrgoK2 Lite dual compression bandage systems for lymphedema need four new HCPCS Level II codes and the same DMEPOS allowable rates that are assigned to the UrgoK2 and UrgoK2 Lite dual compression bandage systems when they are used for venous leg ulcers.

Another commenter urged to establish four new HCPCS Level II codes for home-based lymphedema treatment. The commenter stated that many individuals with advanced lymphedema are homebound, making home-based compression therapy (supported by visiting nurses) their only realistic path to limb preservation and functional improvement. However, traditional lymphedema bandaging presents a significant challenge, and studies show that only around 25% of compression applications are performed correctly, leading to inconsistent pressure, discomfort, and poor adherence. In contrast, the UrgoK2 and UrgoK2 Lite dual compression bandage systems, featuring calibrated layers and clear visual pressure indicators, achieve correct application in nearly 90% of cases, resulting in better clinical outcomes and compliance. The commenter concluded that the absence of appropriate HCPCS Level II codes and adequate

reimbursement rates makes it impossible to prescribe UrgoK2 and UrgoK2 Lite dual compression bandage systems for home use.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" to describe UrgoK2 Lite for a lower limb with an ankle circumference of 9 3/4"- 12 1/2".

CMS maintains that the individual components of the UrgoK2 Lite are appropriately described by existing HCPCS Level II codes based on their physical characteristics, specifically their elastic and inelastic stretch properties, consistent with how other gradient compression bandage products are currently coded. The presence of additional design features or system-level engineering does not establish that the individual bandage components perform a function that is not already described by the existing HCPCS Level II code set.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

While the commenters noted higher payment amounts when this item is used to treat venous leg ulcers, ultimately the method for determining payment for surgical dressings and lymphedema compression treatment items are different in statute and regulation, so it would not be unexpected for this item to have a different payment amount when used to treat lymphedema rather than a wound.

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 8 yards of short stretch bandaging and 12 yards of long stretch bandaging, the total Medicare payment amount would be $8 \times \$1.70 + 12 \times \$1.55 = \$32.20$.

Pricing Indicator = 40

UrgoK2 Lite (Ankle Circumference of 7 1/8"- 9 3/4") - HCP251231FDGRY

Request to establish a new HCPCS Level II code to identify UrgoK2 Lite for a lower limb with an ankle circumference of 7 1/8"- 9 3/4".

Applicant's suggested language: AXXXX, "Dual compression lymphedema bandage system (both short and long stretch therapy) providing 20 mmHg compression to a lower limb with an ankle circumference of 18-25 cm (7 1/8"- 9 3/4")"

Summary of Applicant's Submission

URGO Medical submitted a request to establish a new HCPCS Level II code to identify UrgoK2 Lite providing moderate compression for a lower limb with an ankle circumference of 18-25 cm (7 1/8"- 9 3/4"). UrgoK2 Lite is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is a dual compression system, composed of short stretch and a long stretch bandage. UrgoK2 Lite is indicated for treatment of adults with lower limb lymphedema where moderate compression is recommended. Its exclusive PresSure System with pressure spot indicators on both bandages, aids application of recommended therapeutic pressure (20 mmHg) at the correct stretch and correct overlap. UrgoK2 Lite is a two-layer, multi-component compression system designed to deliver continuous, consistent, and comfortable compression therapy to individuals with lower extremity lymphedema. UrgoK2 Lite dual compression system ensures continuous 24/7 compression regardless of an individual's activity level. KTECH Lite Layer 1 is a short-stretch non-elastic bandage which provides compression, protection, and absorbency. This short-stretch bandage has moderate working pressure when an individual is walking and delivers 80 percent of the prescribed therapeutic compression. KPress Layer 2 is a cohesive long-stretch elastic bandage which has high resting pressure when an individual is at rest and provides the additional compression necessary to achieve the prescribed therapeutic compression. Because UrgoK2 Lite is more permeable to air and much thinner than most lymphedema compression bandages, users experience better breathability and mobility for long-term wear.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" describe UrgoK2 Lite for a lower limb with an ankle circumference of 7 1/8"- 9 3/4". While this two-layer compression system is indicated for treatment of venous stasis ulcers and venous edema, it also is used for lymphedema treatment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 7 yards of short stretch bandaging and 8 yards of long stretch bandaging, the total Medicare payment amount would be $7 \times \$1.70 + 8 \times \$1.55 = \$24.30$.

Pricing Indicator = 40

Summary of Public Feedback

URGO Medical disagreed with CMS' preliminary determinations. They stated that traditional compression bandages are not calibrated to work together, making it challenging for lymphedema professionals and users to consistently achieve the required 20 - 40 mmHg of therapeutic compression across all activity levels (walking, sitting, sleeping).

Instead, the UrgoK2 dual compression systems address this gap through four engineered features: calibrated compression where short and long stretch components are precisely calibrated to maintain therapeutic compression in all users' positions; interlocking layers where bandage layers form a scaffold-like structure that prevents slipping or migration; presSure system indicators where visual spot indicators eliminate guesswork, ensuring correct stretch and compression levels, and absorbent & breathable fabric where the first layer manages lymphorrhea and breathable second layer improves users' comfort and compliance, enabling 24/7 wear.

The commenter stated that when this product is used for venous leg ulcers, each layer of the UrgoK2 system is assigned the same HCPCS Level II code A6452, and the 2026 Total Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) allowable rate for UrgoK2 is \$120.96 and \$163.80 based on an ankle circumference. UrgoK2 Lite is assigned HCPCS Level II code A6449 for one layer and A6452 for another layer, and the 2026 total DMEPOS allowable rate for UrgoK2 Lite is \$82.02 and \$116.60 based on an ankle circumference. URGO Medical does not sell their products directly, they use distributors. The commenters added that the UrgoK2 and UrgoK2 Lite dual compression bandage systems for lymphedema need four new HCPCS Level II codes and the same DMEPOS allowable rates that are assigned to the UrgoK2 and UrgoK2 Lite dual compression bandage systems when they are used for venous leg ulcers.

Another commenter urged to establish four new HCPCS Level II codes for home-based lymphedema treatment. The commenter stated that many individuals with advanced lymphedema are homebound, making home-based compression therapy (supported by visiting nurses) their only realistic path to limb preservation and functional improvement. However, traditional lymphedema bandaging presents a significant challenge, and studies show that only around 25% of compression applications are performed correctly, leading to inconsistent pressure, discomfort, and poor adherence. In contrast, the UrgoK2 and UrgoK2 Lite dual compression bandage systems, featuring calibrated layers and clear visual pressure indicators, achieve correct application in nearly 90% of cases, resulting in better clinical outcomes and compliance. The

commenter concluded that the absence of appropriate HCPCS Level II codes and adequate reimbursement rates makes it impossible to prescribe UrgoK2 and UrgoK2 Lite dual compression bandage systems for home use.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" to describe UrgoK2 Lite for a lower limb with an ankle circumference of 7 1/8" - 9 3/4".

CMS maintains that the individual components of the UrgoK2 Lite are appropriately described by existing HCPCS Level II codes based on their physical characteristics, specifically their elastic and inelastic stretch properties, consistent with how other gradient compression bandage products are currently coded. The presence of additional design features or system-level engineering does not establish that the individual bandage components perform a function that is not already described by the existing HCPCS Level II code set.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

While the commenters noted higher payment amounts when this item is used to treat venous leg ulcers, ultimately the method for determining payment for surgical dressings and lymphedema compression treatment items are different in statute and regulation, so it would not be unexpected for this item to have a different payment amount when used to treat lymphedema rather than a wound.

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 7 yards of short stretch bandaging and 8 yards of long stretch bandaging, the total Medicare payment amount would be $7 \times \$1.70 + 8 \times \$1.55 = \$24.30$.

Pricing Indicator = 40

UrgoK2 (Ankle Circumference of 9 3/4"- 12 1/2") - HCP2512311TPQC

Topic/Issue

Request to establish a new HCPCS Level II code to identify UrgoK2 for a lower limb with an ankle circumference of 9 3/4"-12 1/2".

Applicant's suggested language: AXXXX, "Dual compression lymphedema bandage system (both short and long stretch therapy) providing 40mm Hg compression to a lower limb with an ankle circumference of 25-32 cm (9 3/4"-12 1/2")"

Summary of Applicant's Submission

URGO Medical submitted a request to establish a new HCPCS Level II code to identify UrgoK2 providing high compression for lower limb with an ankle circumference of 25-32 cm (9 3/4"- 12 1/2"). UrgoK2 is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is a dual compression system, composed of short stretch and a long stretch bandage. UrgoK2 is indicated for treatment of adults with lower limb lymphedema where high compression is recommended. Its exclusive PresSure System with pressure spot indicators on both bandages aids application of recommended therapeutic pressure (40 mmHg) at the correct stretch and correct overlap. UrgoK2 is a two-layer, multi-component compression system designed to deliver continuous, consistent, and comfortable compression therapy to individuals with lower extremity lymphedema. UrgoK2 dual compression system ensures continuous 24/7 compression regardless of an individual's activity level. KTECH Layer 1 is a short-stretch non-elastic bandage which provides compression, protection, and absorbency. This short-stretch bandage has high working pressure when an individual is walking and delivers 80 percent of the prescribed therapeutic compression. KPress Layer 2 is a cohesive long-stretch elastic bandage which has high resting pressure when an individual is at rest and provides the additional compression necessary to achieve the prescribed therapeutic compression. Because UrgoK2 is more permeable to air and much thinner than most lymphedema compression bandages, users experience better breathability and mobility for long-term wear.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" describe UrgoK2 for a lower limb with an ankle circumference of 9 3/4"-12 1/2". While this two-layer compression system is indicated for treatment of venous stasis ulcers and venous edema, it also is used for lymphedema treatment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 payment fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 8 yards of short stretch bandaging and 12 yards of long stretch bandaging, the total Medicare payment amount would be $8 \times \$1.70 + 12 \times \$1.55 = \$32.20$.

Pricing Indicator = 40

Summary of Public Feedback

URGO Medical disagreed with CMS' preliminary determinations. They stated that traditional compression bandages are not calibrated to work together, making it challenging for lymphedema professionals and users to consistently achieve the required 20 - 40 mmHg of therapeutic compression across all activity levels (walking, sitting, sleeping).

Instead, the UrgoK2 dual compression systems address this gap through four engineered features: calibrated compression where short and long stretch components are precisely calibrated to maintain therapeutic compression in all users' positions; interlocking layers where bandage layers form a scaffold-like structure that prevents slipping or migration; presSure system indicators where visual spot indicators eliminate guesswork, ensuring correct stretch and compression levels, and absorbent & breathable fabric where the first layer manages lymphorrhea and breathable second layer improves users' comfort and compliance, enabling 24/7 wear.

The commenter stated that when this product is used for venous leg ulcers, each layer of the UrgoK2 system is assigned the same HCPCS Level II code A6452, and the 2026 Total Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) allowable rate for UrgoK2 is \$120.96 and \$163.80 based on an ankle circumference. UrgoK2 Lite is assigned HCPCS Level II code A6449 for one layer and A6452 for another layer, and the 2026 total DMEPOS allowable rate for UrgoK2 Lite is \$82.02 and \$116.60 based on an ankle circumference. URGO Medical does not sell their products directly, they use distributors. The commenters added that the UrgoK2 and UrgoK2 Lite dual compression bandage systems for lymphedema need four new HCPCS Level II codes and the same DMEPOS allowable rates that are assigned to the UrgoK2 and UrgoK2 Lite dual compression bandage systems when they are used for venous leg ulcers.

Another commenter urged to establish four new HCPCS Level II codes for home-based lymphedema treatment. The commenter stated that many individuals with advanced lymphedema are homebound, making home-based compression therapy (supported by visiting nurses) their only realistic path to limb preservation and functional improvement. However, traditional lymphedema bandaging presents a significant challenge, and studies show that only around 25% of compression applications are performed correctly, leading to inconsistent pressure, discomfort, and poor adherence. In contrast, the UrgoK2 and UrgoK2 Lite dual compression bandage systems, featuring calibrated layers and clear visual pressure indicators, achieve correct application in nearly 90% of cases, resulting in better clinical outcomes and compliance. The

commenter concluded that the absence of appropriate HCPCS Level II codes and adequate reimbursement rates makes it impossible to prescribe UrgoK2 and UrgoK2 Lite dual compression bandage systems for home use.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" to describe UrgoK2 for a lower limb with an ankle circumference of 9 3/4"-12 1/2".

CMS maintains that the individual components of the UrgoK2 are appropriately described by existing HCPCS Level II codes based on their physical characteristics, specifically their elastic and inelastic stretch properties, consistent with how other gradient compression bandage products are currently coded. The presence of additional design features or system-level engineering does not establish that the individual bandage components perform a function that is not already described by the existing HCPCS Level II code set.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

While the commenters noted higher payment amounts when this item is used to treat venous leg ulcers, ultimately the method for determining payment for surgical dressings and lymphedema compression treatment items are different in statute and regulation, so it would not be unexpected for this item to have a different payment amount when used to treat lymphedema rather than a wound.

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 8 yards of short stretch bandaging and 12 yards of long stretch bandaging, the total Medicare payment amount would be $8 \times \$1.70 + 12 \times \$1.55 = \$32.20$.

Pricing Indicator = 40

UrgoK2 (Ankle Circumference of 7 1/8" - 9 3/4") - HCP251231WNJ3Q

Topic/Issue

Request to establish a new HCPCS Level II code to identify UrgoK2 for a lower limb with an ankle circumference of 7 1/8" - 9 3/4".

Applicant's suggested language: AXXXX, "Dual compression lymphedema bandage system (both short and long stretch therapy) providing 40mmHg compression to a lower limb with an ankle circumference of 18-25 cm (7 1/8" - 9 3/4")"

Summary of Applicant's Submission

URGO Medical submitted a request to establish a new HCPCS Level II code to identify UrgoK2 providing high compression for a lower limb with an ankle circumference of 18-25 cm (7 1/8" - 9 3/4"). UrgoK2 is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is a dual compression system, composed of short stretch and a long stretch bandage. UrgoK2 is indicated for treatment of adults with lower limb lymphedema where high compression is recommended. Its exclusive PresSure System with pressure spot indicators on both bandages aids application of recommended therapeutic pressure (40 mmHg) at the correct stretch and correct overlap. UrgoK2 is a two-layer, multi-component compression system designed to deliver continuous, consistent, and comfortable compression therapy to individuals with lower extremity lymphedema. UrgoK2 dual compression system ensures continuous 24/7 compression regardless of an individual's activity level. KTECH Layer 1 is a short-stretch non-elastic bandage which provides compression, protection, and absorbency. This short-stretch bandage has high working pressure when an individual is walking and delivers 80 percent of the prescribed therapeutic compression. KPress Layer 2 is a cohesive long-stretch elastic bandage which has high resting pressure when an individual is at rest and provides the additional compression necessary to achieve the prescribed therapeutic compression. Because UrgoK2 is more permeable to air and much thinner than most lymphedema compression bandages, users experience better breathability and mobility for long-term wear.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" describe UrgoK2 for a lower limb with an ankle circumference of 7 1/8" - 9 3/4". While this two-layer compression system is indicated for treatment of venous stasis ulcers and venous edema, it also is used for lymphedema treatment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 7 yards of short stretch bandaging and 8 yards of long stretch bandaging, the total Medicare payment amount would be $7 \times \$1.70 + 8 \times \$1.55 = \$24.30$.

Pricing Indicator = 40

Summary of Public Feedback

URGO Medical disagreed with CMS' preliminary determinations. They stated that traditional compression bandages are not calibrated to work together, making it challenging for lymphedema professionals and users to consistently achieve the required 20 - 40 mmHg of therapeutic compression across all activity levels (walking, sitting, sleeping).

Instead, the UrgoK2 dual compression systems address this gap through four engineered features: calibrated compression where short and long stretch components are precisely calibrated to maintain therapeutic compression in all users' positions; interlocking layers where bandage layers form a scaffold-like structure that prevents slipping or migration; presSure system indicators where visual spot indicators eliminate guesswork, ensuring correct stretch and compression levels, and absorbent & breathable fabric where the first layer manages lymphorrhea and breathable second layer improves users' comfort and compliance, enabling 24/7 wear.

The commenter stated that when this product is used for venous leg ulcers, each layer of the UrgoK2 system is assigned the same HCPCS Level II code A6452, and the 2026 Total Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) allowable rate for UrgoK2 is \$120.96 and \$163.80 based on an ankle circumference. UrgoK2 Lite is assigned HCPCS Level II code A6449 for one layer and A6452 for another layer, and the 2026 total DMEPOS allowable rate for UrgoK2 Lite is \$82.02 and \$116.60 based on an ankle circumference. URGO Medical does not sell their products directly, they use distributors. The commenters added that the UrgoK2 and UrgoK2 Lite dual compression bandage systems for lymphedema need four new HCPCS Level II codes and the same DMEPOS allowable rates that are assigned to the UrgoK2 and UrgoK2 Lite dual compression bandage systems when they are used for venous leg ulcers.

Another commenter urged to establish four new HCPCS Level II codes for home-based lymphedema treatment. The commenter stated that many individuals with advanced lymphedema are homebound, making home-based compression therapy (supported by visiting nurses) their only realistic path to limb preservation and functional improvement. However, traditional lymphedema bandaging presents a significant challenge, and studies show that only around 25% of compression applications are performed correctly, leading to inconsistent pressure, discomfort, and poor adherence. In contrast, the UrgoK2 and UrgoK2 Lite dual compression bandage systems, featuring calibrated layers and clear visual pressure indicators, achieve correct application in nearly 90% of cases, resulting in better clinical outcomes and compliance. The

commenter concluded that the absence of appropriate HCPCS Level II codes and adequate reimbursement rates makes it impossible to prescribe UrgoK2 and UrgoK2 Lite dual compression bandage systems for home use.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A6599, "Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each" and A6597, "Gradient compression bandage roll, elastic long stretch, linear yard, any width, each" to describe UrgoK2 for a lower limb with an ankle circumference of 7 1/8"- 9 3/4".

CMS maintains that the individual components of the UrgoK2 Lite are appropriately described by existing HCPCS Level II codes based on their physical characteristics, specifically their elastic and inelastic stretch properties, consistent with how other gradient compression bandage products are currently coded. The presence of additional design features or system-level engineering does not establish that the individual bandage components perform a function that is not already described by the existing HCPCS Level II code set.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

While the commenters noted higher payment amounts when this item is used to treat venous leg ulcers, ultimately the method for determining payment for surgical dressings and lymphedema compression treatment items are different in statute and regulation, so it would not be unexpected for this item to have a different payment amount when used to treat lymphedema rather than a wound.

The payment rules and pricing associated with the existing HCPCS Level II codes A6599 and A6597 apply to this product, if covered. The current 2026 fee schedule amount for HCPCS Level II code A6599 is \$1.70 and for HCPCS Level II code A6597 is \$1.55. These codes are billed per linear yard. For example, if the kit contains a roll of 7 yards of short stretch bandaging and 8 yards of long stretch bandaging, the total Medicare payment amount would be $7 \times \$1.70 + 8 \times \$1.55 = \$24.30$.

Pricing Indicator = 40

Synchrony® - HCP2601028L5RB

Topic/Issue

Request to establish a new HCPCS Level II code to identify Synchrony®.

Applicant's suggested language: XXXXX, "External upper extremity powered system for user-directed volitional hand movement; wearable; rechargeable"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify Synchrony®. Synchrony® received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 5, 2025. Synchrony® is available as a system or individual kit. The Synchrony® system is a functional electrical stimulation (FES) device and a powered muscle stimulator. Synchrony® system is an externally worn, integrated upper extremity device. The system consists of a wearable stimulator, wireless sensor, surface electrodes, cables, and charging equipment that are designed to function together as a unified system and do not have independent clinical utility when used separately. The Synchrony® system is used to enable intentional hand opening and closing in adults with upper-limb paresis due to upper motor neuron injury by translating user biological intent into proportional electrical stimulation of the affected forearm musculature. The device delivers an externally generated, programmed electrical stimulation to the forearm muscles following user-directed intent or preprogrammed regimens established by a healthcare professional and may be adjusted by the user within preset ranges. The transcutaneous electrical stimulation furnished by the device is administered via externally applied surface electrodes connected to the system. The Synchrony® system is packaged and supplied as a reusable, wearable, rechargeable individual kit furnished by prescription for single-individual use, with all components necessary to deliver the intended function provided together as an integrated system for repeated home use.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes Synchrony®.

Synchrony® is an externally worn functional electrical stimulation device, and the cyclical neuromuscular electrical stimulation mode delivers repetitive stimulation to targeted muscles, aiding in muscle re-training. Like other items and services classified under HCPCS Level II code A9270, Synchrony® does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The Synapse Synchrony® does not meet the following conditions:

Can withstand repeated use – The applicant has indicated that the Synapse Synchrony® is not rented or used by successive patients in customary clinical practice. Per the applicant, the system is prescribed, programmed, and configured for single-patient use based on an individual patient's neurologic impairment, forearm anatomy, and functional goals.

Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years – The applicant has indicated that the Synchrony® System does not have an expected lifetime of at least three years. Per the applicant, under normal conditions of use, the manufacturer specifies an estimated service life of approximately one year for the core system components.

Finally, although the applicant requested that this item be a prosthetic device, per National Coverage Determination 160.12, FES devices are classified as DME. As this device does not meet all five of the conditions for it to be classified as DME, it cannot be classified as DME, and therefore it has no Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

Synapse Biomedical disagreed with CMS' published preliminary determinations. The commenter requested that CMS reconsider its preliminary determinations to recognize the Synchrony® System within the DME benefit category and suggested that the Synchrony® System is described by HCPCS Level II code E0738. The commenter acknowledged that their initial application was developed under a prosthetic framework, with single-patient use and lump-sum purchase assumptions and clarified that this characterization did not accurately reflect the device's true technical capabilities. The commenter noted that part of this inaccuracy stemmed from a typographical error in the application. The commenter asserted that the Synchrony® System's core components, the stimulator and sensor, are designed and validated for a minimum three-year useful life. These components can be sanitized, reprogrammed, recalibrated, and redeployed for successive patients, and meet all statutory criteria for DME under 42 CFR § 414.202. The commenter further stated that the device is appropriate for home use, serves a medical purpose, and has no utility for individuals without neurological impairment.

Although the Synchrony® System utilizes electrical stimulation as one component of therapy, the commenter noted it should not be viewed as a conventional neuromuscular electrical stimulation (NMES) device. The Synchrony® System employs contralaterally controlled functional electrical stimulation (CCFES), a closed-loop system driven by real-time user intent and bilateral movement coordination, rather than the pre-set stimulation patterns used in conventional NMES devices. The device functions as an upper-extremity rehabilitation system intended to restore functional movement and improve motor recovery, making its therapeutic purpose consistent with other rehabilitation technologies that CMS has previously recognized within the DME benefit category.

The commenter stated that multiple randomized controlled trials and subsequent meta-analyses have demonstrated that CCFES provides clinically meaningful improvements in upper-extremity motor recovery and consistently outperforms conventional NMES interventions. A recently published multicenter randomized controlled trial found that patients treated with CCFES exceeded established thresholds for clinically meaningful recovery on the Upper Extremity Fugl-Meyer Assessment at six months.

The commenter suggested that the existing HCPCS Level II code E0738, "Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components and accessories" accurately describes the Synchrony® system's function and should be applied. Although the Synchrony® system and the device currently described by HCPCS Level II code E0738 utilize different technological mechanisms, both systems share the same fundamental rehabilitation objective: facilitating upper-extremity recovery through active user participation, motor re-education, and neuroplastic adaptation following stroke. The commenter inferred that CMS' recognition of E0738 demonstrates that upper-extremity neurorehabilitation systems intended to facilitate motor re-education and recovery can appropriately fall within the DME benefit category.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, "Non-covered item or service" to describe Synchrony®.

CMS notes the following per the FDA 510(k) regulatory pathway device description, the Synchrony® System supports three primary therapeutic modes: CCFES, cyclical neuromuscular electrical stimulation (cNMES), and functional task practice (FTP). These three therapeutic modes collectively define the overall function of the Synchrony® system; therefore, characterizing the device solely as a CCFES system does not fully reflect its described functionality.

Like other items and services classified under HCPCS Level II code A9270, Synchrony® does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The Synapse Synchrony® does not meet the following conditions:

Can withstand repeated use – The applicant previously indicated that the Synchrony® System is not rented or used by successive patients in customary clinical practice. According to the applicant's original HCPCS Level II application, the system is prescribed, programmed, and configured for single-patient use based on an individual patient's neurologic impairment, forearm anatomy, and functional goals.

As part of its public meeting comments, the applicant revised this position and now states that the Synchrony® System's components are designed for repeated use in home and clinical environments and can be reset, reprogrammed, cleaned, and reassigned to successive users. In support of this claim, the applicant submitted cleaning validation reports and related testing documentation.

While the submitted reports demonstrate that certain components of the system can be cleaned following simulated contamination, they do not appear to validate reuse between successive patients. The cleaning validation reports evaluate the sensor, motor point probe, sensor boot, and cable, but do not appear to assess the Synchrony® Stimulator. Furthermore, the reports appear to be directed toward routine cleaning and maintenance rather than reprocessing for multi-patient use. For example, the reports describe cleaning procedures involving the application and removal of artificial soil using household cleaning products and repeatedly characterize cleaning as part of routine device maintenance. The applicant's Home Healthcare report further states that the device does not require professional hygienic maintenance and that cleaning can be performed by a lay operator.

Based on our review, the submitted documentation does not appear to address several issues necessary to establish suitability for multi-patient reuse, including:

- Disinfection between patients;
- Elimination of microorganisms;
- Prevention of cross-contamination; and
- Validation of a reprocessing protocol for successive patient use.

Additionally, the Life Expectancy of Synchrony System Components report states that the stimulator's lifetime assessment relies on "internal testing for device cleaning (REF 20-3000-151)." However, REF 20-3000-151 appears to evaluate only the sensor and motor point probe and does not appear to assess the stimulator itself. As a result, it remains unclear what evidence supports the cleaning and reusability of the stimulator, particularly given the applicant's change from a single-patient-use to a multi-patient-use designation.

Absent documentation demonstrating validated reprocessing procedures and reuse between successive patients, we do not consider the Synchrony® System to satisfy this condition.

Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years- The applicant previously indicated that the Synchrony® System did not have an expected useful life of at least three years. In its HCPCS Level II application and associated documentation, the applicant stated that under normal conditions of use the core system components had an estimated service life of approximately one year. Consistent with these statements, the July 2024 IEC 60601-1-11 Home Healthcare report references the Clinician and Patient Manuals and identifies an

expected service life of one year for the sensor, stimulator, electrode cable, and motor point probe, and 90 days for electrodes.

As part of its public meeting comments, the applicant now asserts that the one-year service-life references were typographical errors and has submitted a Life Expectancy of Synchrony System Components report claiming a three-year useful life for the stimulator and sensor. However, the applicant's earlier submissions contain multiple references to a one-year service life, including statements in the HCPCS Level II application and patient manual. Accordingly, we do not view the one-year service-life references as isolated typographical errors but rather as prior representations regarding the expected service life of the device.

The applicant's more recent life-expectancy analysis concludes that the stimulator and sensor have a three-year expected life based primarily on battery-cycle calculations. Specifically, the analysis assumes a battery specification of 500 recharge cycles, an estimated charging frequency of approximately three times per week, and approximately 468 charging cycles over a three-year period. Based on these assumptions, the applicant concludes that the expected service life exceeds three years.

However, the applicant has not submitted testing specifically demonstrating a three-year useful life. The testing provided includes IEC 60601-1 General Safety testing, IEC 60601-1-11 Home Healthcare testing, biocompatibility testing, and cleaning validation testing. While these reports support the safety and intended operation of the device, they are not life-expectancy evaluations and do not independently demonstrate a three-year service life.

In addition, the submitted life-expectancy analysis does not include field performance data, reliability analyses, failure-rate data, warranty experience, accelerated aging studies, or long-term durability testing demonstrating that the device can reliably function for at least three years under normal conditions of use. Instead, the conclusion appears to rely primarily on engineering assumptions and battery-cycle calculations.

We also note a discrepancy between the applicant's earlier and later documentation. The July 2024 Home Healthcare report identifies a one-year expected service life for the stimulator and sensor, whereas the May 2026 Life Expectancy report identifies a three-year service life for the stimulator and sensor, a one-year service life for the cable, a three-month service life for the boot, and a 1.5-year service life for the charger. The applicant has not adequately reconciled these differing representations. Finally, the submitted testing appears to have been conducted by the manufacturer's own laboratory rather than by independent third-party testing organizations. We did not identify any indication in the submitted reports that the testing was performed or certified by an independent third-party laboratory.

To support a determination that the Synchrony® System has an expected life of at least three years, we would need additional evidence, including independent third-party life-expectancy testing and detailed reports supporting the analyses referenced in the life-

expectancy report. Such evidence should include real-world durability testing, simulated aging studies, reliability analyses, and supporting documentation for the standards cited in Sections 6.3.1.3.1 and 7.3.1.3.1. For the Synchrony® Stimulator and Sensor, we request detailed testing reports addressing, as applicable:

- Electrical testing under extreme conditions;
- Drop testing;
- Push testing;
- Ingress protection testing;
- Label durability testing;
- Temperature testing;
- Humidity testing; and
- Battery testing

Absent such information, we do not consider the Synchrony® System to satisfy this condition.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Sternum Protector - HCP251229E0XN7

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Sternum Protector.

Applicant's suggested language: XXXXX, "Sternum Protector Pad"

Summary of Applicant's Submission

D3D, LLC submitted a request to establish a new HCPCS Level II code to identify the Sternum Protector. The Sternum Protector is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Sternum Protector is a hands-free protective pad designed to be worn over clothing with adjustable straps, specifically intended to aid recovery following open heart or thoracic surgery. The device is indicated for individuals with thoracic chest injuries or those recovering from open heart surgery. The Sternum Protector addresses significant limitations of current alternatives, such as folded blankets or heart-shaped pillows, which are not consistently available and may increase the risk of infection or falls. The device provides continuous, 24-hour protection to the surgical site, and users are instructed to grasp the pad during activities that may cause sudden chest movement, such as coughing, sneezing, or laughing, thereby reducing the risk of wound dehiscence. Additionally, the Sternum Protector supports recommended sternal precautions by encouraging the use of handles rather than hands when rising from a seated position. Clinical evidence indicates that coughing and sneezing can exert between 60 and 90 pounds of pressure on the sternum, which may compromise surgical wires and necessitate further operative intervention. It is prescribed by a physician for a duration determined by individual healing needs, typically ranging from two to twelve weeks, and is worn as a harness secured with straps and buckles. Each unit is individually packaged for individual use and is supplied with a 30-day non-transferable warranty against defects.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type" describes the Sternum Protector.

The Sternum Protector is a protective pad designed for comfort and safe mobility after a sternotomy and is intended to reduce impact pressure to the chest in the event of an accident. The Sternum Protector is similar to other products in HCPCS Level II code E0700.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The Sternum Protector does not meet the following conditions:

Can withstand repeated use - The Sternum Protector is a single patient use device and cannot withstand repeated use (rental by successive patients).

Is primarily and customarily used to serve a medical purpose - The Sternum Protector is not used to treat an illness or injury or improve a malformed body member. It is used for safety purposes to protect the patient's body/chest following open heart surgery.

The Sternum Protector is also not a brace. Regulations at 42 CFR 410.1 defines the term brace to mean a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. The Sternum Protector is not used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0700 apply to this product. Items or services described by HCPCS Level II code E0700 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

D3D, LLC disagreed with CMS' published preliminary determinations. The commenters asserted that the Sternum Protector should instead be classified as a thoracic orthotic device or receive a new HCPCS Level II code to specify it as a therapeutic sternal stabilization device. They stated that existing HCPCS Level II codes are either too broad, too narrow, or non-therapeutic. Specifically, the commenters stated that the Sternum Protector is not an accessory or general safety equipment, and therefore it is not accurately described by HCPCS Level II code E0700 "Safety equipment, device or accessory, any type."

The commenters emphasized that the purpose of the Sternum Protector is not just for general safety precautions, but it is prescribed to serve a medical purpose for the prevention of post-sternotomy and thoracic surgical complications following surgery or injury. The commenters asserted that the Sternum Protector addresses an unmet clinical need for a consistent, hands-free, and medically designed method of providing controlled mechanical stabilization of the sternum during well-defined treatment periods of recovery, and it is intended for the management of a postoperative condition.

The commenters stated that the Sternum Protector provides structural support during a medically vulnerable period, consistent with the concept of orthotic function in the regulations at 42 CFR §410.1. The commenters further emphasized that the CMS regulations do not require a device to maintain complete immobilization to satisfy the concept of restriction, only clinically meaningful restriction or control of motion, which this device provides. The commenters stated that while the Sternum Protector does not fully immobilize the thorax, it incorporates a semi-rigid, high-density foam core that provides external thoracic support to a surgically weakened sternum and restricts harmful sternal micromotion during recovery without eliminating functional mobility. The commenters further discussed the structural elements of the device that resist deformation under load, maintain shape during use, and redistribute mechanical forces applied to the anterior chest wall.

The commenters stated that the Sternum Protector can last for longer than three years and may be used by multiple patients when appropriately inspected and conditioned. The commenters stated that the Sternum Protector is constructed of durable materials designed to maintain structural integrity, fastening performance, and functional effectiveness over multiple use cycles. The commenters clarified that the single-patient labeling reflects infection-control and clinical distribution practices, but not an inherent inability of the device to withstand repeated use.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type" to describe the Sternum Protector.

We acknowledge that the Sternum Protector may be effective and useful in providing stabilization and preventing clinical complications during recovery following thoracic surgery or injury. The Sternum Protector is a protective pad designed for comfort and safe mobility after a sternotomy and is intended to reduce impact pressure to the chest in the event of an accident. While the Sternum Protector may address an unmet medical need, the applicant stated it can also be useful by offering chest protection even in the absence of illness or injury. The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar items or services that are medical in nature into categories for the purpose of efficient claims processing. As such, the Sternum Protector is similar to other products in HCPCS Level II code E0700.

Final Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

The Sternum Protector Pad does not meet the definition of Orthosis or DME. This item functions as a protective cushion worn over the chest during recovery from surgery. The item is intended to support, protect and reduce pain of the surgical site during coughing, sneezing, and other activities.

This item is not a brace. Regulations at 42 CFR 410.1 defines the term brace to mean a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. The Sternum Protector is not used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

This item is not DME.

As stated in the preliminary benefit category determination, the Sternum Protector cannot be rented as it is a single patient use device and cannot withstand repeated use (rental by successive patients). Furthermore, the Sternum Protector is not used to treat an illness or injury or improve a malformed body member. The item may also be useful in the absence of illness or injury.

Therefore, the device is not appropriately classified within the Medicare DMEPOS benefit category.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0700 apply to this product. Items or services described by HCPCS Level II code E0700 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

CoreTech® Sternocostal Orthosis - HCP2512301TRQK

Topic/Issue

Request to establish a new HCPCS Level II code to identify the CoreTech® sternocostal orthosis.

Applicant's suggested language: XXXXX, "Sternocostal orthosis, rigid, costochondral junction compression achieved by circumferential and shoulder straps with dorsal compression via anterior panel"

Summary of Applicant's Submission

Vive Health, LLC submitted a request to establish a new HCPCS Level II code to identify the CoreTech® sternocostal orthosis. The CoreTech® sternocostal orthosis is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). It is intended for nonoperative management of individuals with costochondritis and related chest wall disorders requiring targeted sternocostal stabilization. Costochondritis is a musculoskeletal condition involving inflammation, strain, or tearing of the costochondral cartilage connecting the ribs to the sternum. These joints allow normal chest wall expansion during respiration; however, injury or inflammation can result in significant chest pain, tenderness, referral pain and functional limitation. Because respiration causes repetitive motion and separation at the injured costochondral and costosternal joints, healing is frequently prolonged. Individuals may adopt shallow breathing patterns to avoid pain, which can further impair ventilation efficiency and contribute to muscle fatigue and anxiety. The costosternal and costochondral joints are not naturally immobilized when injured. Continuous chest wall motion during respiration disrupts healing and perpetuates pain. Effective nonoperative management requires stabilization of the sternum and ribs while maintaining functional respiratory movement. The orthosis applies controlled circumferential compression to draw the ribs medially, while adjustable shoulder straps assist in maintaining excessive clavicle and first rib elevation, thoracic alignment and stability. A rigid anterior panel provides dorsal compression to the sternum, limiting excessive motion at the costochondral junctions during respiration and movement. This multi-point stabilization reduces mechanical stress on inflamed or injured cartilage while allowing controlled chest expansion to support functional breathing. By limiting excessive motion of the sternum and ribs, the orthosis supports healing of costochondral injuries and reduces pain associated with chest wall movement during daily activities.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes the CoreTech® sternocostal orthosis.

The CoreTech® sternocostal orthosis is constructed of semi-rigid and elastic materials and does not restrict motion. Therefore, it is similar to other devices currently described under existing HCPCS Level II code A4467.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Federal regulations at 42 Code of Federal Regulations (CFR) 410.2 defines the term brace to mean a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

While information suggests that the anterior and posterior panels of the device may be semi-rigid, we do not believe the device as described restricts motion. Based on the information provided, the CoreTech® Sternocostal Orthosis appears to function as a compression garment rather than an orthosis consistent with the definition of a brace under 42 CFR 410.2. The application emphasizes controlled circumferential compression, functional respiratory movement, and controlled chest expansion. The device is described as limiting excessive motion at the costochondral junctions, providing stabilization of the sternum and ribs, and reducing mechanical stress while allowing controlled chest expansion, with repeated emphasis on stabilizing, limiting excessive motion, and allowing functional respiration. In addition, there is no direct indication that the remainder of the product, including the straps that wrap around the torso and extend over the shoulders, as well as the circumferential components, is non-elastic. Based on the applicant's own functional claims, these components must be elastic or semi-elastic. The repeated references to controlled circumferential compression, allowing functional respiratory movement, and controlled chest expansion necessarily imply elastic compliance. Controlled circumferential compression cannot be achieved using non-elastic materials, and accommodation for respiration and shoulder movement requires flexibility. Non-elastic materials would either loosen during movement or overly restrict breathing and upper body motion.

Moreover, the submission for the CoreTech® Sternocostal Orthosis does not provide mechanical testing, structural specifications, or clinical evidence demonstrating sufficient motion restriction to qualify the device as a rigid or semi-rigid brace that restricts motion. In the absence of objective data demonstrating measurable restriction of motion and medical necessity consistent with brace coverage requirements, CMS does not have sufficient evidence at this time to support classification of the device as a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4467 apply to this product. Items or services described by HCPCS Level II code A4467 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

Vive Health, LLC and other commenters disagreed with CMS' published preliminary determinations. The commenters stated that HCPCS Level II code A4467, "Belt, strap, sleeve,

garment, or covering, any type” does not adequately describe the CoreTech® device’s semi-rigid structural components, specific anatomical targeting, and orthotic function. The commenters requested that CMS reconsider its preliminary determination, establish a new HCPCS Level II L code, and confirm that the CoreTech® sternocostal orthosis fits within Medicare’s brace/orthosis benefit category. Commenters stated the device is designed to treat costochondritis and related costosternal/cartilage injuries by stabilizing the costochondral joints. The commenters noted there is currently no orthotic support option for this anatomical joint, unlike braces that are available for the spine, knee, ankle, and other body parts.

The commenters further explained that costochondritis causes pain because the injured cartilage moves with every breath and currently is typically treated only with non-steroidal anti-inflammatory drugs (NSAIDs) and other conservative measures such as rest recommendations. Commenters also claimed that many individuals seen in an emergency department for chest pain are ultimately diagnosed with costochondritis. Some commenters shared personal experiences of suffering from severe costochondritis that did not improve with steroids, NSAIDs, and conservative treatments. These commenters reported they were unable to breathe comfortably, sleep normally, or perform daily activities due to pain. Many commenters emphasized a clinical need for the CoreTech® sternocostal orthosis as a structural support option and claimed new users often experience immediate improvement in breathing. Commenters stated that this device addresses treatment gap for individuals with costochondritis, Tietze syndrome, chest wall strain, post-viral chest wall irritation, and post-traumatic chest inflammation.

The commenters reiterated that Medicare’s regulatory definition of a brace in the regulations at 42 CFR § 410.2 includes semi-rigid devices that support an injured body part, restrict motion, or eliminate motion. The commenters asserted that CMS’ preliminary determinations focused only on motion restriction but did not consider the device’s support function. The commenters stated that the CoreTech® sternocostal orthosis stabilizes the costosternal joints and restricts excessive motion associated with pain and tissue injury by limiting excessive stretching and separation of the cartilage during breathing and chest expansion. The commenters compared the device to lumbosacral orthoses, thoracolumbosacral orthoses, and limb braces, noting that all devices allow some normal movement while restricting harmful movement.

The commenters explained that the device is not a compression garment, and the application language may have unintentionally suggested that interpretation. The commenters distinguished the device from elastic wraps and compression garments, emphasizing its semi-rigid structural design. The commenters stated that the CoreTech® sternocostal orthosis components include a semi-rigid anterior sternal panel, a semi-rigid posterior dorsal panel, interchangeable sternal pads, and a shoulder/torso strap system. The commenters stated the anterior and posterior panels are made from rigid polyamide-6 thermoplastic that was chosen for rigidity and low weight. The commenters clarified that the straps have limited elasticity to accommodate breathing while maintaining stabilization and positioning of the structural components. The commenters emphasized that some elasticity in the straps is necessary to permit respiration and avoid breathing complications.

The commenters discussed that the brace works through lateral stabilization of the ribs, anterior stabilization of the sternum, and controlled shoulder straps that limit excessive rib flare while

still allowing normal breathing. The commenters stated the anterior and posterior panels and pads are the primary therapeutic components by creating opposing forces, while the straps anchor the device, draw the ribs toward the sternum and help create stabilization. The commenters reiterated that the CoreTech® sternocostal orthosis restricts pathological movement at the costochondral joints while preserving necessary chest expansion for breathing.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination and finalizing the determination to:

Establish new HCPCS Level II code L1330, "Thoracic orthosis, sternal and/or sternocostal compression, may include anterior and/or posterior pads, panels, with or without frame, prefabricated, off the shelf" to describe the CoreTech® sternocostal orthosis.

CoreTech® is constructed of semi-rigid materials and functions to support injured structures while restricting pathologic motion. According to the applicant, the CoreTech® sternocostal orthosis is designed to treat individuals with costochondritis and related costosternal/cartilage injuries. The device incorporates semi-rigid anterior and posterior panels, sternal pads, and a strap system that together creates a three-point force mechanism through which force is applied over the sternum, counterforce is applied posteriorly, and stabilization is provided through the strap system. The evidence demonstrates that the device is intended to limit excessive rib flare and cartilage separation while preserving the chest-wall excursion necessary for normal respiration. Specifically, the manufacturer described lateral stabilization of the chest wall, anterior sternal stabilization, and controlled strap stretch that limits excessive rib flare and cartilage spread. The manufacturer further stated that the semi-rigid anterior and dorsal panels resist outward excursion of the ribs during inhalation, holding the chest wall in position so that injured cartilage is not repeatedly stressed, while allowing the physiologic chest-wall motion necessary for ventilation. We also note that the anterior panel is manufactured from polypropylene, a semi-rigid thermoplastic material selected to provide structural support while allowing limited flexibility. Taken together, the evidence demonstrates that the device functions by supporting injured structures and restricting excessive or pathologic motion while preserving normal physiologic movement.

Final Medicare Benefit Category Determination

Back Brace (Orthotic).

Final Medicare Payment Determination

No determination. As a preliminary determination for payment under a new Level II HCPCS code has not yet been developed, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting. At this time, local fee schedule amounts for this item would be established by the DME MACs. Pricing Indicator = 46

Permeaderm® Glove - HCP2512242FV8T

Topic/Issue

Request to revise existing HCPCS Level II code A2017, “Permeaderm glove, each” to update each to per square centimeter.

Applicant's suggested language: A2017, “Permeaderm glove, per sq. cm”

Summary of Applicant's Submission

Avita Medical Inc. submitted a request to revise existing HCPCS Level II code A2017 to update each to per square centimeter. PermeaDerm® glove received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 08, 2016. It is a sheet-type skin substitute product designed to provide wound coverage and support healing by conforming to the wound surface. It is currently described and reimbursed under a HCPCS Level II “per each” descriptor, which no longer adequately describes the item or its clinical use under CMS’ finalized Fiscal Year 2026 Hospital Outpatient Prospective Payment System and Physician Fee Schedule skin substitute policies. Effective January 1, 2026, CMS requires sheet-type skin substitute products to be billed and paid on a per square centimeter basis to ensure standardized reimbursement across sites of service and appropriate scaling to wound size. The existing “per each” descriptor creates billing ambiguity and misalignment with this payment framework.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code A2017, “Permeaderm glove, each” to instead read “Permeaderm glove, per square centimeter” to describe the PermeaDerm® glove.

Summary of Public Feedback

Avita Medical Inc. agreed with CMS’ published preliminary determination. The written comment submitted supported CMS’ preliminary determination to revise HCPCS code A2017, “Permeaderm glove, each” to instead read “Permeaderm glove, per square centimeter” to describe the PermeaDerm® glove.

CMS Final HCPCS Coding Determination

We appreciate the comment provided in response to CMS’ published preliminary determination. Based on the information provided in the application and after consideration of the comment we received, CMS is revising its preliminary coding determination.

Maintain existing HCPCS Level II code A2017, “Permeaderm glove, each” to describe the PermeaDerm® glove.

Upon further review, PermeaDerm® glove is not applied in a manner similarly to nor does it resemble a sheet skin substitute product. As such, we are maintaining the HCPCS Level II code descriptor to appropriately reflect that this product is a non-sheet skin substitute product.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule Final Rule, Medicare payment for this product will be determined by the Medicare Administrative Contractors.

LacertaMatrix - HCP251229N10KE

Topic/Issue

Request to establish a new HCPCS Level II code to identify LacertaMatrix.

Applicant's suggested language: XXXXX, “Lacertamatrix, per sq cm”

Summary of Applicant's Submission

Lacerta Life Sciences LLC submitted a request to establish a new HCPCS Level II code to identify LacertaMatrix. LacertaMatrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 22, 2025. It is a sterile, single-use, collagen matrix comprised of American alligator hyaluronic acid and porcine gelatin collagen. LacertaMatrix is intended for use in the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns; and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb into the wound bed and does not have to be removed. LacertaMatrix is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Lacertamatrix, per square centimeter” to describe LacertaMatrix.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is revising its preliminary coding determination to:

Establish a new HCPCS Level II code A2047, “Lacertamatrix, per square centimeter (add-on, list separately in addition to primary procedure)” to describe LacertaMatrix.

PuraPly® MZ - HCP251231TLX93

Topic/Issue

Request to establish a new HCPCS Level II code to identify PuraPly® MZ.

Applicant's suggested language: XXXXX, “Puraply mz, per mg”

Summary of Applicant's Submission

Organogenesis Inc. submitted a request to establish a new HCPCS Level II code to identify PuraPly® MZ Micronized Wound Matrix (PuraPly® MZ). PuraPly® MZ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on July 1, 2022. PuraPly® MZ consists of micronized porcine collagen intended for the management of wounds. The existing codes to describe wound dressings with animal-derived material(s) with the same intended use are product specific and cannot be used to report PuraPly® MZ. PuraPly® MZ is intended for the management of wounds that include partial and full-thickness wounds; pressure ulcers; venous ulcers; diabetic ulcers; chronic vascular ulcers; tunneled/undermined wounds; surgical wounds (e.g., donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric wounds, wound dehiscence); trauma wounds (e.g., abrasions, lacerations, and skin tears); partial thickness burns; and draining wounds. The dosage depends on the wound size. It is administered by placing PuraPly® MZ directly on the prepared wound bed. The device is intended for single patient use only. PuraPly® MZ is supplied as a dry powder with a particle size of $\leq 1000 \mu\text{m}$. The device is sterile and packaged in a vial sealed in a single pouch.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Puraply mz, per milligram” to describe PuraPly® MZ.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule Final Rule, Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code A2048, “Puraply mz, per milligram” to describe PuraPly® MZ.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule Final Rule, Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Theracor™ - HCP251230XHUL4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Theracor™.

Applicant's suggested language: XXXXX, “Theracor, per cm²”

Summary of Applicant's Submission

Stimlabs LLC submitted a request to establish a new HCPCS Level II code to identify Theracor™. Theracor™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 22, 2025. Theracor™ is a medical device derived from human umbilical cord extracellular matrix and is indicated for the management of a range of acute and chronic wounds. The device is intended to cover, protect, and provide a moist wound environment. As a resorbable device, Theracor™ is aseptically processed and lyophilized to remove moisture while preserving the structural components of the umbilical cord matrix. The device is packaged in sheet form and should be rehydrated prior to applying it to the wound bed. Theracor™ is for single patient use only. The amount of Theracor™ used will be determined by the treating health care provider based on the size of the wound being treated. Theracor™ should be stored in a clean, dry environment at room temperature in an unopened and undamaged package and should be protected from freezing, excessive heat, and high humidity.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Theracor, per square centimeter” to describe Theracor™.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is revising its preliminary coding determination to:

Establish a new HCPCS Level II code A2049, “Theracor, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Theracor™.

Carbon Life - HCP251112EUXTE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Carbon Life.

Applicant's suggested language: QXXXX, "Carbon Life per sq cm"

Summary of Applicant's Submission

Carbon Life Sciences submitted a request to establish a new HCPCS Level II code to identify Carbon Life. Carbon Life is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “wound covering” and “protective barrier.” Carbon Life is a minimally manipulated, dehydrated amnion membrane allograft intended for homologous use. The allograft is derived from the human amniotic membrane, retaining the functional and structural characteristics of the tissue. Carbon Life is terminally sterilized using an aseptic technique. The product is applied as a cover or barrier and is supplied in various sizes for application and is intended for single use only.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Carbon Life, “when intended to serve as a ‘wound covering’ and ‘protective barrier,’ appears to meet the criteria for regulation solely under the section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Carbon life, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the Carbon Life product described in the application and accompanying FDA TRG letter dated November 12, 2025, when intended for use as a “wound covering” and “protective barrier.”

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code Q4207, “Carbon life, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the Carbon Life product described in the application and accompanying FDA TRG letter dated November 12, 2025, when intended for use as a “wound covering” and “protective barrier.”

DermaBind SL Optic™ - HCP2510282XA05

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind SL Optic™.

Applicant's suggested language: Q4xxx, “DermaBind SL Optic per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SL Optic™. DermaBind SL Optic is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as an “ocular wound covering” and “to offer protection from the surrounding environment.” DermaBind SL Optic™ is designed for application directly to acute and chronic wounds of the eye, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind SL Optic™ application includes, but is not limited to, corneal and conjunctival related injuries or defects such as corneal epithelial defects, pterygium repair, fornix reconstruction, and other procedures. DermaBind SL Optic™ is a single-layer amniotic membrane.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, DermaBind SL Optic™, “when intended for use ‘as an ocular wound covering’ and ‘to offer protection from the surrounding environment,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Dermabind sl optic, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the DermaBind SL Optic™ product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended for use as an “ocular wound covering” and “to offer protection from the surrounding environment.”

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code Q4223, “Dermabind sl optic, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the DermaBind SL Optic™ product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended for use as an “ocular wound covering” and “to offer protection from the surrounding environment.”

AmchoMatrix - HCP251223WL54Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmchoMatrix.

Applicant's suggested language: XXXXX, “AmchoMatrix, per square centimeter”

Summary of Applicant's Submission

LifeCell International Pvt Ltd. submitted a request to establish a new HCPCS Level II code to identify AmchoMatrix. AmchoMatrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” and “cover for acute and chronic wounds.” AmchoMatrix is a sterile, minimally manipulated, dehydrated human amnion, intermediate layer, and chorion membrane allograft. AmchoMatrix functions as a protective barrier and provides coverage from the surrounding environment for acute and chronic wounds such as partial and full-thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. Its use is restricted to homologous applications. AmchoMatrix is processed using validated aseptic techniques and is terminally sterilized by gamma irradiation. Dosage is based on the size and location of the wound and is measured in square centimeters. AmchoMatrix must be stored in a clean, dry environment at ambient room temperature. AmchoMatrix is supplied in various sheet sizes and configurations to accommodate clinical needs.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, AmchoMatrix, “when intended for use as a barrier and cover for acute and chronic wounds appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Amchomatrix, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the AmchoMatrix product described in the application and accompanying FDA TRG letter dated October 7, 2025, when intended for use as a “barrier” and “cover for acute and chronic wounds.”

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code Q4243, “Amchomatrix, per square centimeter (add-on, list separately in addition to primary procedure)”.

This coding determination applies to the AmchoMatrix product described in the application and accompanying FDA TRG letter dated October 7, 2025, when intended for use as a “barrier” and “cover for acute and chronic wounds.”

Ceragem Master V6 - HCP260101KNV3E

Topic/Issue

Request to establish a new HCPCS Level II code to identify Ceragem Master V6.

Applicant's suggested language: XXXXX, "Ceragem Master V6"

Summary of Applicant's Submission

Ceragem International, Inc. submitted a request to establish a new HCPCS Level II code to identify Ceragem Master V6. Ceragem Master V6 is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Ceragem Master V6 provides muscle relaxation therapy by delivering heat and soothing massage. It also provides topical radiant infrared heat for temporary relief of minor muscle and joint pain stiffness and tension, temporary relief of minor pain associated with arthritis, and temporary increase in local circulation where applied, as well as relaxation of muscles. It stimulates kneading and stroking of tissues by using an inflatable garment. This device works by identifying the course and segments of the spine with the user lying in the supine position, and a ceramic roller parallel to the spine applies pressure and heat to the paraspinal muscles while moving in the cervical-to-lumbar direction.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes Ceragem Master V6.

Ceragem Master V6 provides muscle relaxation therapy by delivering heat and soothing massage. While this device may be used for temporary relief of minor muscle and joint pain, stiffness, and tension; temporary relief of minor pain associated with arthritis; temporary increase in local circulation where applied; and relaxation of muscles, it may be used in the absence of illness and injury. Like other items and services classified under HCPCS Level II code A9270, Ceragem Master V6 does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Per National Coverage Determination (NCD) 280.1, the Durable Medical Equipment Reference List, massage devices are not DME. They are personal comfort items and are not primarily medical in nature.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, "Non-covered item or service" to describe Ceragem Master V6.

Ceragem Master V6 provides muscle relaxation therapy by delivering heat and soothing massage. While this device may be used for temporary relief of minor muscle and joint pain, stiffness, and tension; temporary relief of minor pain associated with arthritis; temporary increase in local circulation where applied; and relaxation of muscles, it may be used in the absence of illness and injury. Like other items and services classified under HCPCS Level II code A9270, Ceragem Master V6 does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Per National Coverage Determination (NCD) 280.1, the Durable Medical Equipment Reference List, massage devices are not DME. They are personal comfort items and are not primarily medical in nature.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Cool Cube™ - HCP251218D9JD7

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cool Cube™.

Applicant's suggested language: XXXXX, "Qualified pack-out system that maintains the cold chain for temperature-sensitive medications that require a temperature range of 2°C-8°C for 65+ hours without the need for electricity"

Summary of Applicant's Submission

VeriCor LLC submitted a request to establish a new HCPCS Level II code to identify Cool Cube™. Cool Cube™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Cool Cube™ is a medical transport cooler and a qualified pack-out system specifically designed to maintain the cold chain for biologics and other medications requiring temperatures between 2 °C and 8 °C for over 65 hours without electricity. The Cool Cube™ is a reusable, non-significant risk device that employs passive technology, utilizing phase change materials (PCM) and vacuum-insulated panels (VIPs) to provide consistent and superior thermal protection at a set melt/freeze point. The unit is comprised of three components: an exterior carrying case, VIPs, and PCM panels that are solidified in a refrigerator or freezer. It is intended for all ages and suitable for both home use and travel, ensuring safety by preventing drug degradation and ensuring uninterrupted access to viable medication.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to identify Cool Cube™. Cool Cube™ is intended for use as a medical transport cooler designed to maintain the cold chain for temperature-sensitive medications by keeping them within a controlled temperature range during transport and storage. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

VeriCor LLC disagreed with CMS' published preliminary determination. The commenters stated that there is a growing clinical need driven by the rapid expansion of biologic therapies, which represent 5% of prescriptions but account for more than half of all U.S. drug spending. They further noted that millions of individuals managing conditions such as cancer, autoimmune diseases, and diabetes depend on temperature-sensitive medications that require careful handling. As healthcare delivery increasingly shifts toward home-based and individual-administered therapies, individuals are now personally responsible for transporting and storing these medications. However, no standardized reimbursement pathway currently exists to support this need. The commenter stated that providers are forced to bill using miscellaneous codes such as HCPCS Level II code E1399, which leads to manual claim reviews, inconsistent adjudication, frequent denials, and significant administrative burden across Medicare Advantage, Medicaid,

and commercial insurance plans. They further stated that current use of miscellaneous codes is viewed as a temporary workaround requiring extensive documentation and offering uncertain reimbursement outcomes. Because individuals often pay out of pocket or forgo the product entirely, true demand is invisible to the claims system, meaning access is determined by financial means rather than medical necessity. This creates a risk of temperature excursions, reduced medication efficacy, and treatment failure. The commenter stated the product meets CMS' criteria for durable medical equipment, as it is durable, serves a medical purpose, is appropriate for home use, and is reusable. From a cost-benefit perspective, the Cool Cube™ can prevent costly medication replacement following temperature excursions caused by power outages, travel, or emergencies, offering a meaningful return on investment for payers given the high cost of specialty medications.

CMS Final HCPCS Coding Determination

We appreciate the comment provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comment we received, CMS is finalizing its preliminary coding determination. CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to identify Cool Cube™. Cool Cube™ is intended for use as a medical transport cooler designed to maintain the cold chain for temperature-sensitive medications by keeping them within a controlled temperature range during transport and storage. The use of a miscellaneous HCPCS Level II code to bill for a product does not, by itself, establish a claims processing need for a unique HCPCS Level II code. CMS has not received sufficient information to demonstrate that Medicare or other payers have an operational need for a distinct code to identify this product for claims processing purposes.

Kangaroo OMNI™ Thick Formula ENTelliSet and Kangaroo OMNI™ Thick Formula ENTelliSet with Flush Bag - HCP251231TWH4Q

Topic/Issue

Request to establish a new HCPCS Level II code to identify Kangaroo OMNI™ Thick Formula ENTelliSet and Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag and to revise existing HCPCS Level II code B4035, “Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape” to further distinguish thin formulations.

Applicant's suggested language:

1. BXXXX, “Enteral feeding supply kit (thick formula (IDDSI Levels 2, 3, and 4); pump fed, per day, includes but not limited to feeding/flushing syringe, administration set thick tubing, dressings, tape”
2. B4035, “Enteral feeding supply kit (thin formula IDDSI Level 0 and 1); pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape”

Summary of Applicant's Submission

Cardinal Health submitted a request to establish a new HCPCS Level II code to identify Kangaroo OMNI™ Thick Formula ENTelliSet and Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag, and to revise existing HCPCS Level II code B4035 to further distinguish thin formulations. Kangaroo OMNI™ Thick Formula ENTelliSet and Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 2, 2022. Kangaroo OMNI™ Thick Formula ENTelliSet is for individuals who are unable to consume adequate nutrition orally, those who have impaired swallowing (dysphagia), and those with certain medical conditions such as neurological disorders (stroke, Parkinson’s disease), head and neck cancers, or severe gastrointestinal issues, among other conditions. Nutritional support may be administered through various mechanisms, including pumps especially designed for this purpose, which are connected to enteral feeding sets, which are in turn connected with an enteral access device. The current code set includes a single code (HCPCS Level II code B4035) to report supply kits for use with enteral pumps, regardless of whether the tubing provided can accommodate thick formula consistent with the International Dysphagia Diet Standardization Initiative (IDDSI) Levels 2, 3, and 4. This application seeks modification of the HCPCS Level II code B4035 descriptor to limit its use to supply kits intended for thin formula only and to add a new HCPCS Level II code B403X for supply kits designed to administer thick formula. Thick formulas are defined as enteral fluids of smooth consistency that would be categorized as level 2, 3, or 4 drinks within the IDDSI framework. Thick formula may include thin formula with added thickeners; however, the most commonly administered thick “formula” consists of whole foods (either freshly prepared or commercially available blenderized formulas) administered via blenderized tube feeding (BTF). Thick formula has several clinical advantages for certain individuals who require

enteral feeding. Use of BTF is associated with improved outcomes, including reduced gastroesophageal reflux, retching, gagging, constipation, frequency of hospitalization for respiratory disease, and increased diversity of the gut microbiome.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code B4035, “Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape” describes Kangaroo OMNI™ Thick Formula ENTelliSet and the Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag.

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to describe the Kangaroo OMNI™ Thick Formula ENTelliSet or the Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag. HCPCS Level II code B4035 does not include formula thickness requirements, thereby allowing all formula thicknesses to use the same code. The Kangaroo OMNI™ Thick Formula ENTelliSet is similar to other products in HCPCS Level II code B4035.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code B4035 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code B4035 is \$11.38 in rural areas and \$7.12 in nonrural areas.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 39

Summary of Public Feedback

Cardinal Health disagreed with CMS’ published preliminary determinations. The commenter stated that users should have access to medically necessary nutrition support therapies prescribed by their healthcare team, along with the supplies needed to administer those therapies safely. The commenter further asserted that coding and reimbursement policies should recognize clinically meaningful differences in patient needs when supported by appropriate clinical and real-world evidence. In addition, coverage policies should minimize avoidable barriers that increase out-of-pocket costs, delay care, or restrict access to appropriate therapy.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code B4035, "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" to describe Kangaroo OMNI™ Thick Formula ENTelliSet and the Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag.

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to describe the Kangaroo OMNI™ Thick Formula ENTelliSet or the Kangaroo OMNI™ Thick Formula ENTelliSet with flush bag. HCPCS Level II code B4035 does not include formula thickness requirements, thereby allowing all formula thicknesses to use the same code. The code encompasses feeding and flushing syringes, administration set tubing, dressing tape, and other supplies necessary for enteral feeding. The Kangaroo OMNI™ Thick Formula ENTelliSet is similar to other products in HCPCS Level II code B4035.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code B4035 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code B4035 is \$11.38 in rural areas and \$7.12 in nonrural areas.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 39

VYAFUSER™ Pump - HCP2508144JR8W

Topic/Issue

Request to establish a new HCPCS Level II code to identify the VYAFUSER™ pump.

Applicant's suggested language: EXXXX, “Ambulatory infusion pump, specific device-drug combination, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient”

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify external infusion pumps for unique device-drug combinations such as VYALEV™ and the VYAFUSER™ pump. VYALEV™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 16, 2024. VYALEV™, infused via the VYAFUSER™ pump as a device-drug combination, is used for the treatment of advanced Parkinson’s disease. In early 2025, the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) recommended that the VYAFUSER™ pump be billed using existing HCPCS Level II code E0781, “Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient” and HCPCS Level II supply codes A4222, “Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)” and, since the VYAFUSER™ pump uses a syringe-type reservoir, suppliers may also separately bill HCPCS Level II code K0552, “Supplies for external non-insulin drug infusion pump, syringe type cartridge, sterile, each.” After six months of billing, the DME MACs have realized the need for unique HCPCS Level II codes to reflect device-drug combinations. The use of existing HCPCS Level II codes to describe these unique device-drug combinations does not allow for proper claim editing, thus creating claim vulnerabilities. For example, HCPCS Level II code E0781 is also used to bill for the pump used to administer Duopa®, an enterally-infused drug used to treat Parkinson’s disease and often a precursor to the use of VYALEV™. Coding the VYAFUSER™ pump with HCPCS Level II code E0781 has resulted in hundreds of denials (and subsequent appeals) due to “same or similar” denials.

CMS Preliminary HCPCS Coding Determination

Establish new HCPCS Level II code EXXXX, “Ambulatory infusion pump, specific device-drug combination, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient” to identify external infusion pumps for unique device-drug combinations such as the VYAFUSER™ pump.

The VYAFUSER™ pump is a device-drug combination intended to only infuse the drug VYALEV™ for the treatment of advanced Parkinson’s disease. The DME MACs have a claims processing need for establishing a new HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.236(a), if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. The item described by HCPCS Level II code EXXXX has a pricing history because it is an electric ambulatory infusion pump described by HCPCS Level II code E0781. Thus, the preliminary payment determination for new HCPCS Level II code EXXXX is to map the fee schedule amounts for HCPCS Level II code E0781 to this new code.

The 2026 average capped rental non-rural fee schedule amount for HCPCS Level II code EXXXX would be approximately \$314.22 for months 1 through 3 and approximately \$235.66 for months 4 through 13, for a total of \$3,299.26 after 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish new HCPCS Level II code E0788, "Ambulatory infusion pump, specific device-drug combination, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient" to identify external infusion pumps for unique device-drug combinations such as the VYAFUSER™ pump.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

In accordance with regulations at 42 CFR 414.236(a), if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. The item described by

HCPCS Level II code E0788 has a pricing history because it is an electric ambulatory infusion pump described by HCPCS Level II code E0781. Thus, the final payment determination for new HCPCS Level II code E0788 is to map the fee schedule amounts for HCPCS Level II code E0781 to this new code.

The 2026 average capped rental non-rural fee schedule amount for HCPCS Level II code E0788 would be approximately \$314.22 for months 1 through 3 and approximately \$235.66 for months 4 through 13, for a total of \$3,299.26 after 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Supplies for Device-Drug Combination Infusion Pump - HCP250814QVQD0

Topic/Issue

Request to establish a new HCPCS Level II code to identify supplies for a device-drug combination infusion pump.

Applicant's suggested language: AXXXX, "Supplies for maintenance of non-insulin, device-drug combination infusion catheter, per week"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify infusion pump maintenance supplies for unique device-drug combinations such as VYALEV™ and the VYAFUSER™ pump. VYALEV™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 16, 2024. VYALEV™, infused via the VYAFUSER™ pump as a device-drug combination, is used for the treatment of advanced Parkinson's Disease. In early 2025, the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) recommended that the VYAFUSER™ pump be billed using existing HCPCS Level II code E0781, "Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient" and HCPCS Level II supply codes A4222, "Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)" and, since the VYAFUSER™ pump uses a syringe-type reservoir, suppliers may also separately bill HCPCS Level II code K0552, "Supplies for external non-insulin drug infusion pump, syringe type cartridge, sterile, each." After six months of billing, the DME MACs have realized the need for unique HCPCS Level II codes to reflect device-drug combinations. The use of existing HCPCS Level II codes to describe these unique device-drug combinations does not allow for proper claim editing, thus creating claim vulnerabilities. For example, HCPCS Level II code E0781 is also used to bill for the pump used to administer Duopa®, an enterally-infused drug used to treat Parkinson's disease and often a precursor to the use of VYALEV™. Coding the VYAFUSER™ pump using HCPCS Level II code E0781 has resulted in hundreds of denials (and subsequent appeals) due to "same or similar" denials. The establishment of a unique code for the device and a unique code specific to the device for supplies would allow the DME MACs to edit claims accurately, avoid "same or similar" denials and track utilization of these device-drug combinations.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Supplies for maintenance of non-insulin, device-drug combination infusion catheter, per week" to identify supplies for a device-drug combination infusion pump.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.236(a), if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. The item described by HCPCS Level II code AXXXX has a pricing history based on HCPCS Level II code A4222. Thus, the preliminary payment determination for new HCPCS Level II code AXXXX is to map the fee schedule amounts to HCPCS Level II code A4222. The HCPCS Level II code AXXXX “per week” fee is based on 2.5 units of A4222 to account for changing the supplies every 3 days.

Based on the formula that multiplies HCPCS Level II code A4222 by 2.5, the 2026 average non-rural fee schedule amount for HCPCS Level II code AXXXX would be approximately \$124.54. Fee schedules are updated annually.

Pricing Indicator = 34

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code A4228, “Supplies for maintenance of non-insulin, device-drug combination infusion catheter, per week” to identify supplies for a device-drug combination infusion pump.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

In accordance with regulations at 42 CFR 414.236(a), if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. The item described by HCPCS Level II code A4228 has a pricing history based on HCPCS Level II code A4222. Thus, the final payment determination for new HCPCS Level II code A4228 is to map the fee schedule amounts to HCPCS Level II code A4222. The HCPCS Level II code A4228 “per week” fee is based on 2.5 units of HCPCS Level II code A4222 to account for changing the supplies every 3 days.

Based on the formula that multiplies HCPCS Level II code A4222 by 2.5, the 2026 average non-rural fee schedule amount for HCPCS Level II code A4228 is approximately \$124.54. Fee schedules are updated annually.

Pricing Indicator = 34

NTI-duo - HCP2507125MV9M

Topic/Issue

Request to establish a new HCPCS Level II code to identify NTI-duo.

Applicant's suggested language: XXXXX, "Intraoral device to reduce migraine frequency and intensity by minimizing nocturnal pathologic intensity of trigeminal innervation of elevation musculature"

Summary of Applicant's Submission

Boyd Research, Inc. submitted a request to establish a new HCPCS Level II code to identify NTI-duo. NTI-duo received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 20, 2001. NTI-duo is indicated for the prevention of medically diagnosed migraine pain as well as migraine-associated tension-type headaches through the reduction of neuromuscular activity. The NTI-duo is an intraoral device with a specific design that minimizes the nocturnal pathologic intensity of the trigeminally-innervated musculature known to exist in individuals who experience chronic migraine. Maximum and pathologic jaw-clenching intensity can only occur when the opposing posterior and canine teeth are engaging each other or are engaged with a typical "occlusal protective device". In fact, the provision of the typical occlusal protective device allows nocturnal jaw-clenching intensity to increase, resulting in an increase in headache symptoms. The NTI-duo device is a custom-provided intraoral device that provides only for a single anterior point stop at a vertical dimension that minimizes condylar rotation, thereby governing trigeminal innervation to the jaw-clenching muscles to < 30 percent of maximum.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes NTI-duo.

NTI-duo is a custom fabricated device that aids in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing. Like other items and services classified under HCPCS Level II code A9270, NTI-duo does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The NTI-duo does not meet one of the conditions as follows:

Can withstand repeated use – According to the application, the NTI-duo is an intraoral device that is custom-fabricated for each individual. It is our understanding that custom-fabricated medical equipment is manufactured according to the specific measurements and form of the individual's unique anatomy such that the equipment cannot be used by successive patients. Also, we understand that custom-fabricated items are intended for single- individual use for hygienic purposes to prevent cross-contamination. It is important to note that we do not question the effectiveness and usefulness of custom-fabricated medical equipment. However, medical equipment classified as DME must be able to withstand repeated use. This means that medical equipment must be able to be rented, refurbished and used by successive patients.

Since the NTI-duo device does not fulfill this requirement, it does not fall within the DME benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, “Non-covered item or service” to describe NTI-duo.

NTI-duo is a custom fabricated device that aids in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing. Like other items and services classified under HCPCS Level II code A9270, NTI-duo does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Eneura Single–Pulse Transcranial Magnetic Stimulation (sTMS) Neuromodulation System - HCP250812GVKKD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Eneura sTMS Neuromodulation System branded as the SAVI Dual™ Migraine Therapy.

Applicant's suggested language: XXXXX, “Transcranial Magnetic Stimulator, wearable, patient-controlled, for the acute and preventive treatment of migraine and other neurological conditions, FDA-cleared for home use. MicroSIM Rx Card Monthly prescription refill card for cranial neuromodulation TMS therapy”

Summary of Applicant's Submission

Eneura Inc. submitted a request to establish a new HCPCS Level II code to identify Eneura sTMS Neuromodulation System branded as the SAVI Dual™ Migraine Therapy. The SAVI Dual™ Migraine Therapy received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 16, 2023. The SAVI Dual™ Migraine Therapy device is indicated for the acute and prophylactic treatment of migraine headache for individuals 12 years and older. The SAVI Dual™ Migraine Therapy device is a portable, hand-held device that delivers a brief single pulse of magnetic energy at 0.9 Tesla to the back of the head using an ergonomic headband to induce an electrical current in a portion of the brain, called the occipital cortex, to stop or lessen the effects of migraine headaches. The SAVI Dual™ Migraine Therapy device is prescription use only and it is self-administered in the individual's home or office. The user must either insert a SIM chip or connect wirelessly via a cellular connection to use the device for a programmed duration. The programmed duration corresponds to the prescribed months of use. Packaging includes the reusable SAVI Dual™ Migraine Therapy device and monthly disposable prescription cards encoded with the individual's prescription, shipped in tamper-evident, serialized containers.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes SAVI Dual™ Migraine Therapy device.

The SAVI Dual™ Migraine Therapy device is a portable, non-invasive, hand-held device that delivers a brief single pulse of magnetic energy to the back of the head to induce an electrical current in a portion of the brain. Like other items and services classified under HCPCS Level II code A9270, SAVI Dual™ Migraine Therapy does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. The SAVI Dual™ Migraine Therapy device does not meet the following condition:

Can withstand repeated use- The SAVI Dual™ Migraine Therapy device is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients.

Therefore, the SAVI Dual™ Migraine Therapy device cannot be defined as durable medical equipment.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' preliminary determinations by the published deadline.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received by the published deadline, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II code A9270, “Non-covered item or service” to describe SAVI Dual™ Migraine Therapy device.

The SAVI Dual™ Migraine Therapy device is a portable, non-invasive, hand-held device that delivers a brief single pulse of magnetic energy to the back of the head to induce an electrical current in a portion of the brain. Like other items and services classified under HCPCS Level II code A9270, SAVI Dual™ Migraine Therapy does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. The SAVI Dual™ Migraine Therapy device does not meet the following condition:

Can withstand repeated use- The SAVI Dual™ Migraine Therapy device is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients.

Therefore, the SAVI Dual™ Migraine Therapy device cannot be defined as durable medical equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

ExoBand - HCP251230KVQK3

Topic/Issue

This is a request to appeal CMS' previous HCPCS Level II final coding determination that identified ExoBand with HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type," and reassign ExoBand to the existing HCPCS Level II code L2999, "Lower extremity orthosis, not otherwise specified".

Summary of Applicant's Submission

Moveo SRL submitted a request to appeal CMS' previous final coding determination that identified ExoBand with the existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type," and reassign ExoBand to the existing HCPCS Level II code L2999, "Lower extremity orthosis, not otherwise specified. ExoBand is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). ExoBand uses engineered elastic connectors, mechanical tension-adjustment features, and soft tissue-friendly textile architecture, and is designed to support human walking for individuals with motor impairments caused by disabling diseases and health conditions, including those with neurodegenerative diseases such as Parkinson's disease and multiple sclerosis, or those who experienced acute events like stroke or spinal cord injury. It is a lower-extremity assistive device that provides functional support to the hip and lower extremity, improves gait mechanics and walking efficiency, assists with mobility-related functional deficits, and offers therapeutic benefit through biomechanical assistance. ExoBand consists of a belt and two leg loops. These three independent elements are connected to each other by a mechanism that stores energy generated in the first phase of the gait cycle to return it in the second phase, enhancing the thrust of the hip flexors and leading to functional improvement in walking.

CMS Preliminary HCPCS Coding Recommendation

In the Second Biannual 2024 HCPCS Level II coding cycle (prior application HCP240701FNQJ2), CMS concluded that existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes ExoBand. CMS determined that ExoBand is primarily made of elastic material and is similar to other devices in existing HCPCS Level II code A4467. CMS maintains that HCPCS Level II code A4467 describes ExoBand.

ExoBand is primarily composed of elastic material and functions as a supportive wrap or strap. Its design, construction, and intended use are consistent with other items classified under this code. Based on the evidence submitted, ExoBand does not demonstrate structural, mechanical, or functional characteristics that would distinguish it from other products described by HCPCS Level II code A4467.

The materials and studies provided do not show that the device performs structural orthotic functions such as joint stabilization, controlled alignment, application of a three-point pressure system, or delivery of corrective forces at a specific joint. While the ExoBand includes elastic load-bearing elements, adjustable tensioning, and structured hip and thigh components, we

acknowledge these features support functional gait assistance rather than orthotic stabilization or correction. This does not support classification of the ExoBand as a lower-extremity orthosis or assignment to HCPCS Level II code L2999. The functional characteristics are more consistent with HCPCS Level II code A4467.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Regulations at 42 Code of Federal Regulations (CFR) 410.1 defines the term brace to mean a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not meet the definition of a brace. Based on this definition, the preliminary determination is that the ExoBand is not a brace. There is no indication that this product uses rigid or semi-rigid materials that would qualify it as a brace.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4467 apply to this product. Items or services described by HCPCS Level II code A4467 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS maintains that:

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes ExoBand.

ExoBand is primarily composed of elastic material and functions as a supportive wrap or strap. Its design, construction, and intended use are consistent with other items classified under this code. Based on the evidence submitted, ExoBand does not demonstrate structural, mechanical, or functional characteristics that would distinguish it from other products described by HCPCS Level II code A4467.

The materials and studies provided do not show that the device performs structural orthotic functions such as joint stabilization, controlled alignment, application of a three-point pressure system, or delivery of corrective forces at a specific joint. While the ExoBand includes elastic load-bearing elements, adjustable tensioning, and structured hip and thigh components, we acknowledge these features support functional gait assistance rather than orthotic stabilization or correction. This does not support classification of the ExoBand as a lower-extremity orthosis or assignment to HCPCS Level II code L2999. The functional characteristics are more consistent with HCPCS Level II code A4467.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4467 apply to this product. Items or services described by HCPCS Level II code A4467 are not covered under Medicare Part B.

No Medicare payment.

Pricing Indicator = 00

Ankle Foot Orthosis - HCP251211GM5MA

Topic/Issue

Request to establish a new HCPCS Level II code to identify a prefabricated, off-the-shelf version of the existing HCPCS Level II code L1971, as well as, revise existing HCPCS Level II code L1971, “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment,” to further describe the customization of an individual-specific product crafted by an individual with expertise.

Applicant's suggested language:

1. LXXXX, “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, off-the shelf”
2. L1971, “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to describe a prefabricated, off-the-shelf version of the existing HCPCS Level II code L1971, as well as revise existing HCPCS Level II code L1971 to further describe the customization of an individual-specific product crafted by an individual with expertise. Palmetto GBA noticed a substantial increase in usage of the HCPCS Level II code L2999, “Lower extremity orthoses, not otherwise specified” claim submissions that indicate that the custom fitted HCPCS Level II code L1971 is being delivered as an off-the-shelf product.

CMS Preliminary HCPCS Coding Determinations

1. Establish a new HCPCS Level II code LXXXX, “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, off-the shelf” to describe a prefabricated, off-the-shelf ankle foot orthosis with an ankle joint.
2. Revise existing HCPCS Level II code L1971, “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment” to instead read “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise” to describe a custom fitted prefabricated ankle foot orthosis with an ankle joint.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

For new HCPCS Level II code LXXXX, in accordance with regulations at 42 Code of Federal Regulations (CFR) 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II code LXXXX has a pricing history. Items falling under new HCPCS Level II code LXXXX were previously paid for under HCPCS Level II code L1971. When there is a single code that describes two or more distinct complete items (off-the-shelf and custom-fitted items under code L1971), and separate codes are subsequently established for each item (revising HCPCS Level II code L1971 to be used for custom fitted braces falling under current code L1971 and establishing HCPCS Level II code LXXXX to be used for off-the-shelf braces falling under current code L1971), the payment amount that applied to the original HCPCS Level II code L1971 is also applied to both the revised HCPCS Level II code L1971 and new HCPCS Level II code LXXXX. The average 2026 fee schedule amount for HCPCS Level II code L1971 is \$573.18.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determinations to:

1. Establish a new HCPCS Level II code L1972, "Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, off-the shelf" to describe a prefabricated, off-the-shelf ankle foot orthosis with an ankle joint.
2. Revise existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment" to instead read "Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise" to describe a custom fitted prefabricated ankle foot orthosis with an ankle joint.

Final Medicare Benefit Category Determination

Leg Brace.

Final Medicare Payment Determination

For new HCPCS Level II code L1972, in accordance with regulations at 42 Code of Federal Regulations (CFR) 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new HCPCS Level II code L1972 has a pricing history. Items falling under new HCPCS Level II code L1972 were previously paid for under HCPCS Level II code L1971. When there is a single code that describes two or more distinct complete items (off-the-shelf and custom-fitted items under code L1971), and separate codes are subsequently established for each item (revising HCPCS Level II code L1971 to be used for custom fitted braces falling under current code L1971 and establishing HCPCS Level II code L1972 to be used for off-the-shelf braces falling under current code L1971), the payment amount that applied to the original HCPCS Level II code L1971 is also applied to both the revised HCPCS Level II code L1971 and new HCPCS Level II code L1972. The average 2026 fee schedule amount for HCPCS Level II code L1971 is \$573.18.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Omni-Directional Shank/Foot System - HCP251210K9WKV

Topic/Issue

Request to establish a new HCPCS Level II code to identify an omni-directional shank/foot system.

Applicant's suggested language: LXXXX, "Omni-directional light weight foot/shank system"

Summary of Applicant's Submission

Dycor Manufacturing, Inc. submitted a request to establish a new HCPCS Level II code to identify an omni-directional shank/foot system. Passive shank and foot prostheses are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This application is pursuant to a patent pending extracorporeal omni-directional elastic foot/shank system. Individual elasticity of the triple helix pylon is matched to the elasticity of the integrated advanced composite leaf spring foot. Integral alignment of these matched components provides a new level of ankle and foot freedom of motion in all three planes.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II codes L5976, "All lower extremity prostheses, energy storing foot (seattle carbon copy ii or equal)" in conjunction with L5985, "All endoskeletal lower extremity prostheses, dynamic prosthetic pylon" describe the prosthetic components in an omni-directional shank/foot system.

An omni-directional shank/foot system is designed to provide energy storage and dynamic load response within an endoskeletal prosthetic system. In prosthetic design, ankle and foot motion is generally characterized across three planes: sagittal (dorsiflexion and plantarflexion), coronal (inversion and eversion), and transverse (rotational movement). While the applicant asserts that the device provides enhanced motion and energy transfer across all three planes, CMS notes that devices demonstrating clinically meaningful multi-planar ankle motion typically incorporate complex hydraulic or microprocessor-controlled ankle mechanisms.

CMS finds that the application describes an integrated, bonded, and non-separable foot-and-nylon system engineered through user-specific adjustment of elastic and spring characteristics. When reviewing this application, CMS considered the Medicare Functional Classification Level¹ system, commonly known as the "K-levels" that describe an individual's functional mobility potential and helps determine which prosthetic components are appropriate. Upon further review, CMS finds that the system functions primarily as an energy-storing prosthetic foot, rather than a true energy-return (K3) foot. The use of low-viscosity resin transfer molding epoxy and unidirectional carbon fiber composites is typical of energy-storing feet and is also observed in some energy-return designs; however, the reported efficiency values (near 100 percent for the

¹ Medicare Functional Classification Levels - <https://www.cms.gov/training-education/medicare-learning-network-mln/compliance/medicare-provider-compliance-tips/lower-limb-prostheses>

pylon and approximately 95 percent for the foot) alone do not establish energy-return functionality, as many energy-storing (K2/K2+) feet report similarly high efficiency.

The device is preset in a neutral position, cannot be cut, and the foot cannot be separated from the pylon. These features relate to how it is manufactured and adjusted, not to how it performs while walking. Because HCPCS Level II codes are based on functional performance and clinical benefit, not manufacturing design, these characteristics do not justify establishing a new code. To support classification as an energy-return (K3) system, CMS would expect objective gait analyses, evidence of multi-planar dynamic response across variable walking speeds, and functional testing demonstrating true energy return rather than energy storage alone; such evidence was not provided by the applicant.

CMS further notes that component transfer and alignment activities, including zero moment point horizontal re-alignment, which the applicant states are inherent to the provision of an endoskeletal prosthesis, are already incorporated into existing base prosthetic fabrication HCPCS Level II codes (e.g., HCPCS Level II code L5301, “Below knee, molded socket, shin, SACH foot, endoskeletal”).

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes L5976 and L5985 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code L5976 is \$777.11. The current average 2026 fee schedule amount for HCPCS Level II code L5985 is \$348.60.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to assign:

Existing HCPCS Level II codes L5976, “All lower extremity prostheses, energy storing foot (seattle carbon copy ii or equal)” in conjunction with L5985, “All endoskeletal lower extremity

prostheses, dynamic prosthetic pylon” to describe the prosthetic components in an omni-directional shank/foot system.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes L5976 and L5985 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code L5976 is \$777.11. The current average 2026 fee schedule amount for HCPCS Level II code L5985 is \$348.60.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Rollz Motion - HCP240628PHWKW

Topic/Issue

Request to establish Medicare benefit category and Medicare pricing for HCPCS Level II code E0150.

Summary of Applicant's Submission

Rollz Mobility US Inc. submitted a request to establish a new HCPCS Level II code to describe Rollz Motion. Rollz Motion is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Rollz Motion is a rollator and wheelchair combination. It has four large wheels, is heavy duty, foldable, has adjustable handlebars and a solid seat. As a wheelchair, this product has an adjustable solid back in addition to the previously mentioned features. This allows users to stay as active as possible using the Rollz Motion as a rollator and they can transform it into a wheelchair whenever they need more support. This benefits rehabilitation and achieving a more active lifestyle. Over 8.5 million people in the United States of all ages with diseases like multiple sclerosis, Parkinson's disease or amyotrophic lateral sclerosis, or those simply having serious mobility issues may benefit greatly from a combination product like the Rollz Motion. Rollz Motion provides the user with a product for well over five years up to ten years, which they can use in multiple stages of mobility.

CMS Final HCPCS Coding Determination

CMS established HCPCS Level II code E0150, "Combination wheeled walker with seat and transport chair, folding, adjustable or fixed height" to describe the Rollz Motion, effective October 1, 2025.

Preliminary Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined that there is no Medicare DMEPOS benefit category for the Rollz Motion Performance model. The following preliminary Medicare benefit category determination applies to the Rollz Motion 2.1 and Rollz Motion models as described by HCPCS Level II code E0150.

Durable Medical Equipment.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.

5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. In the First Biannual 2025 HCPCS Level II coding cycle, CMS had originally determined that the Rollz Motion 2.1 and Rollz Motion models did not meet the condition related to being appropriate for use in the home. However, based on additional information provided by the applicant after the coding cycle, we have now determined that these Rollz Motion models are appropriate for use in the home in rare cases where both a walker and transport chair are both medically necessary for use in the home and therefore meet all requirements to be classified as DME.

Preliminary Medicare Payment Determination

HCPCS Level II code E0150 is a combination of a folding wheeled walker described by HCPCS Level II code E0143 and a transport chair described by HCPCS Level II code E1038.

Regulations at 42 CFR 414.236(b) specify that when the codes for different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

Based on 2024 claims data, the most recent year for which full claims data are available, there were 501,442 allowed services for a combination of the purchase and rental of walkers for 489,650 beneficiaries under HCPCS Level II code E0143 and 172,664 allowed services for rental of transport chairs for 32,562 beneficiaries under HCPCS Level II code E1038. The weights used to calculate the weighted average of the fee schedule amounts for HCPCS Level II codes E0143 and E1038 are 0.7439 for HCPCS Level II code E0143 ($501,442 \div 674,106$) and 0.2561 for HCPCS Level II code E1038 ($172,664 \div 674,106$). In computing the weighted average purchase fee schedule amount, the purchase fee schedule amount for HCPCS Level II code E1038 is derived by multiplying the capped rental fee schedule amount by ten. For example, the 2026 purchase fee schedule amount for HCPCS Level II code E1038 for rural Alabama is \$227.20 (rental fee \$22.72 multiplied by 10). The 2026 purchase fee schedule amount for HCPCS Level II code E0143 for rural Alabama is \$106.25. The weighted average purchase fee schedule amount for HCPCS Level II codes E0143 and E1038 for rural Alabama is \$137.23 ($\$106.25 \times 0.7439 + \227.20×0.2561). The resulting 2026 purchase fee schedule amounts for HCPCS Level II code E0150 would be approximately \$135.76, on average, for rural areas, and \$89.79, on average, for nonrural areas. Since the items described by HCPCS Level II code E0150 meet the definition of inexpensive DME at section 414.220(a) of regulations, payment would be made on a rental or purchase basis. The fee schedule amounts for purchase of used equipment would be equal to 75 percent of the fee schedule amounts for purchase of new equipment, and the fee schedule amounts for rental would be equal to 10 percent of the fee schedule amounts for purchase of new equipment.

Pricing Indicator = 32

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The Medicare payment amount for Level II HCPCS code E0150 will be established as described in the preliminary payment determination. Per this determination, the resulting 2026 purchase fee schedule amounts for HCPCS Level II code E0150 would be approximately \$135.76, on average, for rural areas, and \$89.79, on average, for nonrural areas.

Pricing Indicator = 32

NeuRx® Diaphragm Pacing System External Pulse Generator - HCP26010276W44

Topic/Issue

Request to establish a new HCPCS Level II code to identify an External Pulse Generator for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "External pulse generator, battery-powered, for use with diaphragm pacing system, includes stimulation control, timing, and safety monitoring, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify External Pulse Generator (EPG) for the NeuRx® Diaphragm Pacing System. The EPG is a component of the NeuRx® Diaphragm Pacing System, which was approved by the Food and Drug Administration (FDA) under a Premarket Approval (PMA) on March 31, 2023. The EPG is a lightweight, battery-powered, four-channel external stimulator designed for use with implanted diaphragm pacing electrodes. The EPG houses the microprocessor, stimulation circuitry, liquid crystal display, user interface, and integrated safety features, and delivers independently regulated biphasic electrical stimulation across four channels. The EPG is body-worn prosthetic control unit that interfaces directly with percutaneously externalized implanted electrodes and serves as an essential neuroprosthetic component rather than a supply or accessory. The EPG controls the intensity, timing, and sequence of diaphragm stimulation to restore rhythmic diaphragm contractions and support breathing in individuals who lack voluntary respiratory control. The device is indicated to allow the individual to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours per day. The EPG delivers stimulation at physician-programmed settings, and no user adjustments to stimulation parameters are required. The EPG is packaged either as a component of the NeuRx® kit at therapy initiation or as a separate replacement supply and is intended for repeated daily use in the home or clinical settings.

CMS Preliminary HCPCS Coding Determination

1. Establish a new HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe the NeuRx® Diaphragm Pacing System External Pulse Generator.
2. Discontinue existing HCPCS Level II code L8696, "Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each."

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device and, as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications. Accordingly, CMS proposes to discontinue existing HCPCS Level II code L8696, as the proposed HCPCS Level II code LXXXX would encompass all external replacement components of the phrenic

nerve stimulation device, including items currently described under HCPCS Level II code L8696.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determinations to:

1. Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe the NeuRx® Diaphragm Pacing System External Pulse Generator.
2. Discontinue existing HCPCS Level II code L8696, "Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each."

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device and, as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications. Accordingly, CMS finalizing its preliminary coding determination to discontinue existing HCPCS Level II code L8696, as the proposed HCPCS Level II code L8697 would encompass all external replacement components of the phrenic nerve stimulation device, including items currently described under HCPCS Level II code L8696.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Alkaline Battery - HCP26010255JNV

Topic/Issue

Request to establish a new HCPCS Level II code to identify an alkaline battery replacement for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "External alkaline power battery for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify an alkaline battery replacement for the NeuRx® Diaphragm Pacing System. The battery is a non-implantable, user-replaceable C-size primary battery available in either alkaline or lithium chemistry. The alkaline battery provides the electrical power needed for the operation of the external pulse generator (EPG), enabling delivery of physician-programmed electrical stimulation to the diaphragm. Battery usage duration depends on the battery chemistry and device settings; the alkaline battery provides approximately 96 hours of operation. The battery is packaged individually for replacement, supplied separately from the EPG, and furnished as needed to maintain continuous system operation.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe an alkaline battery replacement for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that

initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. The diaphragm muscle itself may be healthy, but it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe an alkaline battery replacement for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Lithium Battery - HCP260102EDYL9

Topic/Issue

Request to establish a new HCPCS Level II code to identify lithium battery replacement for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "External lithium power battery for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a lithium battery replacement for the NeuRx® Diaphragm Pacing System. The battery is a non-implantable, user-replaceable C-size primary battery available in either alkaline or lithium chemistry. The lithium battery provides the electrical power needed for the operation of the external pulse generator (EPG), enabling delivery of physician-programmed electrical stimulation to the diaphragm. Battery usage duration depends on the battery chemistry and device settings; the lithium battery provides up to 500 hours of operation. The battery is packaged individually for replacement, supplied separately from the EPG, and furnished as needed to maintain continuous system operation.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a lithium battery replacement for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that

initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a lithium battery replacement for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Test Plug - HCP260102G41KN

Topic/Issue

Request to establish a new HCPCS Level II code to identify a test plug for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, “Diagnostic test plug for use with diaphragm pacing system, replacement”

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a test plug for the NeuRx® Diaphragm Pacing System. The test plug is a non-implantable diagnostic connector designed to interface with the external pulse generator for troubleshooting and system verification. The test plug simulates electrode impedance, allowing clinicians or trained caregivers to confirm proper output and function of the diaphragm pacing system without connecting to implanted electrodes. The test plug is for diagnostic purposes only: it enables verification of device performance and electrical output to distinguish between external component or generator issues and implanted electrode issues, thereby supporting safe and effective system management. The test plug is packaged as a single, reusable diagnostic accessory and is supplied as a replacement item.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to separately establish a new HCPCS Level II code to identify a test plug for the NeuRx® Diaphragm Pacing System. The test plug for the NeuRx® Diaphragm Pacing System is a diagnostic connector used to verify external pulse generator output during troubleshooting allowing clinicians to confirm proper device function. For Medicare, this item is not separately paid.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination. CMS has not identified a program operating need for Medicare or other insurers to separately establish a new HCPCS Level II code to identify a test plug for the NeuRx® Diaphragm Pacing System. The test plug for the NeuRx® Diaphragm Pacing System is a diagnostic connector used to verify external pulse generator output during troubleshooting allowing clinicians to confirm proper device function. For Medicare, this item is not separately paid.

NeuRx® Diaphragm Pacing System Connector Holder - HCP260102TFEED

Topic/Issue

Request to establish a new HCPCS Level II code to identify a connector holder for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, “Adhesive connector holder with integrated clip, for securement of external electrode connector used with diaphragm pacing system, replacement”

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a connector holder for the NeuRx® Diaphragm Pacing System. The connector holder is a hypoallergenic adhesive patch with an integrated plastic clip designed to secure the external electrode connector to the skin at the percutaneous exit site. The connector holder functions to stabilize the electrode connector; prevent traction or strain on the implanted electrode wires; and maintain consistent orientation of the connector to ensure safe and reliable electrical contact during diaphragm pacing therapy. The connector holder should be replaced at recommended intervals —typically every three to seven days or sooner if soiled—to maintain hygiene and secure fixation. The connector holder is packaged either as part of a kit at therapy initiation or as a separately supplied replacement component, commonly provided in multi-unit packs for periodic replacement during normal system use.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “External accessory for use with implantable phrenic nerve stimulation device, replacement, each” to describe a connector holder for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a connector holder for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Surface Electrode Pad - HCP2601020JMF

Topic/Issue

Request to establish a new HCPCS Level II code to identify a surface electrode pad for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "Surface anode electrode pad for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a surface electrode pad for the NeuRx® Diaphragm Pacing System. The surface electrode pad is an adhesive, single-use device designed to be used exclusively in conjunction with the backup indifferent electrode interconnect. It functions as an external anode when the implanted anode or return pathway cannot be utilized. The primary function of the surface electrode pad is to provide the external return electrode necessary to complete the stimulation circuit, enabling physician-programmed electrical stimulation to continue being delivered through the diaphragm pacing neuroprosthesis without interruption. The use of the surface electrode pad is determined by clinical need when the implanted return pathway is unavailable. The surface electrode pad is packaged as a single-use replacement component, typically supplied in packs.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a surface electrode pad for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a surface electrode pad for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Surface-Electrode Interconnect - HCP2601026P96M

Topic/Issue

Request to establish a new HCPCS Level II code to identify a surface electrode interconnect for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "Backup indifferent electrode interconnect for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a surface electrode interconnect for the NeuRx® Diaphragm Pacing System. The surface electrode interconnect is a non-implantable, temporary device designed for contingency use when the implanted indifferent electrode fails or is unable to function. It connects directly to the existing electrode connector and is used in combination with a surface anode patch to re-establish the electrical return pathway required for diaphragm pacing. The function of this device is to restore the stimulation circuit and enable continued delivery of physician-programmed electrical stimulation to the diaphragm, allowing neuroprosthetic therapy to proceed safely without interruption and without the need for emergent surgical reimplantation. The surface electrode interconnect is packaged as a single replacement unit intended for one individual.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a surface electrode interconnect for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a surface electrode interconnect for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Strain Relief Boot - HCP2601024LG5F

Topic/Issue

Request to establish a new HCPCS Level II code to identify a strain relief boot for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, “Strain relief boot for use with diaphragm pacing system, replacement”

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a strain relief boot for the NeuRx® Diaphragm Pacing System. The strain relief boot is a non-implantable, flexible, medical-grade urethane component that surrounds and reinforces the electrode connector block at the percutaneous exit site of implanted electrode leads. The function of the strain relief boot is to protect the electrode connector interface, stabilize electrode terminations, and reduce mechanical stress on the implanted leads, thereby preventing wire fatigue or breakage and preserving the integrity of the neurostimulation interface. The strain relief boot is packaged as a single replacement component.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “External accessory for use with implantable phrenic nerve stimulation device, replacement, each” to describe a strain relief boot for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that

initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a strain relief boot for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Patient Cable - HCP260102A063D

Topic/Issue

Request to establish a new HCPCS Level II code to identify a patient cable for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, “Patient cable for use with external pulse generator and implanted diaphragm pacing electrodes, replacement”

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a patient cable for the NeuRx® Diaphragm Pacing System. The patient cable is a medical-grade, five-conductor, silicone-jacketed, shielded electrical cable designed to connect the External Pulse Generator (EPG) to the externalized electrode connector of the implanted diaphragm pacing system. The cable features a push-pull locking connector on the EPG end and a precision-molded, mated connector on the electrode-connector end to ensure stable and secure electrical contact. The function of the patient cable is to transmit programmed electrical stimulation signals generated by the EPG to the implanted diaphragm electrodes. It is not interchangeable with cables used for other neurostimulation or respiratory devices. The patient cable is packaged either as part of the patient kit at therapy initiation or as a separately supplied replacement component when cable replacement is required due to wear or compromised electrical continuity.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “External accessory for use with implantable phrenic nerve stimulation device, replacement, each” to describe a patient cable for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Section 1861(s)(8) of the Social Security Act specifies that prosthetic devices (other than dental) replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an

internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Although the NeuRx® Diaphragm Pacing System does not replace the diaphragm muscle itself, as the muscle remains intact and capable of contraction, it replaces the phrenic nerve signal that initiates diaphragmatic contraction. In cases of high spinal cord injury, the neural pathway that signals the diaphragm to contract is permanently inoperative or malfunctioning. Although the diaphragm muscle itself may be healthy, it cannot function as intended without proper nerve signaling. The NeuRx® Diaphragm Pacing System effectively replaces this lost neural activation function. By delivering electrical impulses directly to the diaphragm, it replicates the signals that the brain can no longer transmit, thereby enabling the diaphragm to contract and allowing the patient to breathe. Thus, the NeuRx® Diaphragm Pacing System replaces the function of the permanently impaired neural pathway that controls breathing, thereby restoring the ability to breathe.

Additionally, stimulation is delivered to the phrenic nerve motor point through four intramuscular electrodes implanted into the diaphragm. Thus, the NeuRx® Diaphragm Pacing System is a phrenic nerve stimulator. Per National Coverage Determination 160.19, phrenic nerve stimulators are a prosthetic device.

Preliminary Medicare Payment Determination

As HCPCS Level II code LXXXX includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each" to describe a patient cable for the NeuRx® Diaphragm Pacing System.

The external replacement components of the phrenic nerve stimulation device are all associated with the implantable device, and as such may be identified using a single HCPCS Level II code to describe all applicable accessories that are the subject of these applications.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

As HCPCS Level II code L8697 includes a variety of miscellaneous external accessories for use with an implantable phrenic nerve stimulation device, local fee schedule amounts would be established for the various different external accessories by the MACs for use in paying any covered claims.

Pricing Indicator = 46

NeuRx® Diaphragm Pacing System Electrode Connector Socket Kit - HCP2601025KXFL

Topic/Issue

Request to establish a new HCPCS Level II code to identify an electrode connector socket kit for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "Electrode connector socket kit for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify an electrode connector socket kit for the NeuRx® Diaphragm Pacing System. The electrode connector socket is a non-implantable, containing precision metal connector sockets pre-crimped to match the geometry of implanted electrode pins, along with a molded carrier and medical-grade silicone strain-relief components. The function of the kit is to restore reliable electrical continuity between implanted electrodes and the external patient cable when connector sockets become loose, damaged, or unable to maintain stable signal transmission. The use of the electrode connector socket kit is determined by clinical need when connector integrity is compromised. The kit is packaged as a single replacement set containing all components necessary to repair the electrode connector interface for one individual.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify an electrode connector socket kit for the NeuRx® Diaphragm Pacing System. The external replacement components and/or accessories included in the kit are already individually described under HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each;" therefore, establishing a new HCPCS Level II code is duplicative.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination. CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify an electrode connector socket kit for the NeuRx® Diaphragm Pacing System. The external replacement components and/or accessories included in the kit are already individually described under HCPCS Level II code L8697, "External accessory for use with implantable

phrenic nerve stimulation device, replacement, each;" therefore, establishing a new HCPCS Level II code is duplicative.

NeuRx® Diaphragm Pacing System Patient Kit - HCP260102XDWK0

Topic/Issue

Request to establish a new HCPCS Level II code to identify a patient kit for the NeuRx® Diaphragm Pacing System.

Applicant's suggested language: XXXXX, "External control and patient interface kit for use with diaphragm pacing system, replacement"

Summary of Applicant's Submission

Synapse Biomedical submitted a request to establish a new HCPCS Level II code to identify a patient kit for the NeuRx® Diaphragm Pacing System. This kit includes all required external components necessary to operate a diaphragm pacing neuroprosthesis following implantation. Components include external pulse generators, patient cables, connector holders, diagnostic accessories, power supplies, and user instructions. The patient kit provides external control, power, and interface elements required to deliver physician-programmed electrical stimulation to the diaphragm for respiratory control. The kit is non-implantable, furnished for home use, and may be replaced on an outpatient basis. The patient kit is packaged as a single set of interdependent external components intended for use by one patient and supplied as a complete replacement unit when individual component substitution is not clinically appropriate.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify a patient kit for the NeuRx® Diaphragm Pacing System. The external replacement components and/or accessories included in the kit are already individually described under HCPCS Level II code LXXXX, "External accessory for use with implantable phrenic nerve stimulation device, replacement, each;" therefore, establishing a new HCPCS Level II code is duplicative.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary determination.

CMS Final HCPCS Coding Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary coding determination. CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify a patient kit for the NeuRx® Diaphragm Pacing System. The external replacement components and/or accessories included in the kit are already individually described under HCPCS Level II code L8697, "External accessory for use with implantable phrenic nerve

stimulation device, replacement, each;” therefore, establishing a new HCPCS Level II code is duplicative.

FSYX™ Ocular Pressure Adjusting Pump - HCP2501014576E

Topic/Issue

Request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump.

Applicant's suggested language: EXXXX, “External ocular negative pressure system, electrical, programmable pressure-adjusting pump”

Summary of Applicant's Submission

Balance Ophthalmics, Inc. submitted a request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump. FSYX™ Ocular Pressure Adjusting Pump (FSYX™) received De Novo classification by the Food and Drug Administration (FDA) on June 27, 2024. The FSYX™ is a prescription-only device system for the treatment of glaucoma in individuals with measured intraocular pressure (IOP) ≤ 21 mmHg, often referred to as normal tension glaucoma (NTG). This system consists of single-use individually fitted eye goggles connected to a durable, programmable pressure-modulating pump, and specialized vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles, thereby lowering an individual's IOP during sleep. Open-angle glaucoma (OAG) is characterized by elevation of IOP, which results in progressive vision loss due to atrophy of the optic nerve and loss of retinal ganglion cells. NTG is a form of OAG characterized by the presence of glaucomatous optic nerve damage despite a measured IOP of ≤ 21 mmHg, which is considered the upper limit of statistically normal IOP. Treatment of NTG represents a particular challenge for providers because achieving IOP reduction targets is more difficult in individuals whose pre-treatment IOP levels are measured at ≤ 21 mmHg during the day. A leading cause of continued glaucoma progression in NTG individuals is uncontrolled nocturnal elevations in IOP, in which pressures increase to levels that can cause damage to the optic nerve (Dubey et al., 2020). The FSYX™ specifically addresses the critical and often overlooked nocturnal pressure spikes that can significantly impact glaucoma progression, despite adequately controlled IOP during the day. By providing consistent nocturnal IOP reduction, the FSYX™ slows vision loss in individuals with daytime IOP under 21 mmHg. A recent pivotal study demonstrates that the FSYX™ provides statistically and clinically significant IOP lowering during use, with lower pressures beginning with device activation and remaining consistent throughout device wear. Again, the FSYX™ is indicated for the reduction of IOP during sleep in adults with OAG and IOP ≤ 21 mmHg who are currently using or have undergone another IOP lowering treatment. The FSYX™ system is intended to be used by the individual in their home while sleeping as prescribed by a physician. The FSYX™ packaging includes the durable FSYX™ pump, which connects to the FSYX™ goggles through tubing supplied with the goggles to create a vacuum system inside the goggles, and an initial supply of the FSYX™ goggles, which are fitted around an individual's eyes to create a seal.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code EXXXX, “External ocular negative pressure pump, electric” to describe FSYX™ Ocular Pressure Adjusting Pump.

Medicare Benefit Category Determination

CMS determined that the FSYX™ Ocular Pressure Adjusting Pump is durable medical equipment and published that determination on November 14, 2025.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 Code of Federal Regulations (CFR) 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions. We have not identified any comparable items to the FSYX™ Ocular Pressure Adjusting Pump, and therefore the fee schedule amounts for this item may be established using supplier price lists.

Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). The Department of Veterans Affairs (VA) National Acquisition Center (NAC) shows that the VA has a contract in place for the FSYX™ Ocular Pressure Adjusting Pump from May 15, 2025, until May 14, 2030, at a price of \$13,927.14 for each unit. Using this price results in a 2026 monthly capped rental fee schedule amount of approximately \$897.02 on average for months 1 through 3, and approximately \$672.77 on average for months 4 through 13, resulting in a total capped payment of \$9,418.76 per beneficiary should there be 13 months of continuous use.

Pricing Indicator = 36

Summary of Public Feedback

Balance Ophthalmics, Inc. (Balance) agreed with the preliminary HCPCS Level II coding determination for the FSYX™ Ocular Pressure Adjusting Pump (FSYX™ Pump) and encouraged CMS to finalize the decision. The commenter noted that the code descriptor accurately describes the components of the FSYX™ Pump, and it will facilitate appropriate claims processing by third-party payors. While Balance agreed with CMS’ preliminary payment

determination that there are no comparable items to the FSYX™ Pump, Balance disagreed with the preliminary payment determination for the FSYX™ Pump. As part of their comments, Balance submitted invoices from various insurers (ranging in price from \$15,000 to \$60,000), as well as an updated contract rate for the FSYX™ Pump VA NAC for \$17,914.57 per unit. Per Balance, the VA contract rate increased in price from \$13,927.14 to \$17,914.57 due to increases in costs of supply, manufacturing, personnel, and other activities since Balance submitted their HCPCS Level II application in December 2024. Balance stated that the \$13,927.14 price that CMS used in the preliminary payment determination, which results in a 2026 total capped payment of \$9,418.76 per unit, understates the commercial pricing for the FSYX Pump™. Balance stated that a government contract or VA price may not fully capture the commercial market price at which a product is furnished to Medicare and commercially insured beneficiaries through accredited DMEPOS suppliers. Furthermore, Balance stated that government contract pricing does not incorporate the full range of costs associated with accreditation, claims submission, documentation, coverage determinations, appeals, and ongoing beneficiary services that DMEPOS suppliers incur in furnishing the device to patients. Per Balance, VA pricing may establish a minimum commercial price, but that pricing alone is insufficient to reflect actual commercial pricing for Medicare. Balance requested that CMS use the median of their submitted pricing data (\$21,000) when gap-filling for the final payment determination. Balance stated that when applicants provided CMS with updated, validated payor data, CMS has updated the commercial pricing for the item accordingly in the final payment determination.

CMS Final HCPCS Coding Determination

We appreciate the comments submitted in response to CMS' published preliminary determinations. After reviewing the application and carefully considering the information provided by commenters, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code E2403, "External ocular negative pressure pump, electric" to describe FSYX™ Ocular Pressure Adjusting Pump.

Medicare Benefit Category Determination

CMS determined that the FSYX™ Ocular Pressure Adjusting Pump is DME and published that determination on November 14, 2025.

Final Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate

the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions. We have not identified any comparable items to the FSYX™ Ocular Pressure Adjusting Pump, and therefore the fee schedule amounts for this item may be established using supplier price lists.

The applicant has sent us two VA invoices from 2024 for a one-month rental of the FSYX™ Ocular Pressure Adjusting Pump for \$1,447.73. Per 42 CFR 414.229(b)(2), the capped rental purchase price for this monthly rental amount is calculated by multiplying \$1,447.73 by 10, which is \$14,477.30. The applicant also sent us seventeen invoices from 2024 and 2025 from other commercial payers with purchase prices ranging from \$15,000 to \$60,000, the supplier's submitted charge. The median of the nineteen invoice purchase prices is \$21,000.00.

Using this \$21,000.00 price results in a 2026 monthly capped rental fee schedule amount of approximately \$1,352.58 for months 1 through 3, and approximately \$1,014.44 for months 4 through 13 for HCPCS Level II code E2403, resulting in a total capped payment of \$14,202.09 per beneficiary should there be 13 months of continuous use.

Pricing Indicator = 36

FSYX™ Ocular Pressure Adjusting Goggles - HCP250101BJQNN

Topic/Issue

Request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump goggles.

Applicant's suggested language: AXXXX, "Supplies and accessories for external ocular negative pressure system, 1 month supply"

Summary of Applicant's Submission

Balance Ophthalmics, Inc. submitted a request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump goggles. FSYX™ Ocular Pressure Adjusting Pump (FSYX™) received De Novo classification by the Food and Drug Administration (FDA) on June 27, 2024. The FSYX™ is a prescription-only device system for the treatment of glaucoma in individuals with measured intraocular pressure (IOP) ≤ 21 mmHg, often referred to as normal tension glaucoma (NTG). This system consists of single-use, individually fitted eye goggles connected to a durable, programmable pressure-modulating pump, and specialized vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles, thereby lowering an individual's IOP during sleep. Open-angle glaucoma (OAG) is characterized by elevation of IOP, which results in progressive vision loss due to atrophy of the optic nerve and loss of retinal ganglion cells. NTG is a form of OAG characterized by the presence of glaucomatous optic nerve damage despite a measured IOP of ≤ 21 mmHg, which is considered the upper limit of statistically normal IOP. Treatment of NTG represents a particular challenge for providers because achieving IOP reduction targets is more difficult in individuals whose pre-treatment IOP levels are measured at ≤ 21 mmHg during the day. A leading cause of continued glaucoma progression in NTG individuals is uncontrolled nocturnal elevations in IOP, in which pressures increase to levels that can cause damage to the optic nerve (Dubey et al., 2020). The FSYX™ specifically addresses the critical and often overlooked nocturnal pressure spikes that can significantly impact glaucoma progression, despite adequately controlled IOP during the day. By providing consistent nocturnal IOP reduction, the FSYX™ slows vision loss in individuals with daytime IOP under 21 mmHg. A recent pivotal study demonstrates that the FSYX™ provides statistically and clinically significant IOP lowering during use, with lower pressures beginning with device activation and remaining consistent throughout device wear. Again, the FSYX™ is indicated for the reduction of IOP during sleep in adult individuals with OAG and IOP ≤ 21 mmHg who are currently using or have undergone another IOP-lowering treatment. The FSYX™ device system is intended to be used by the individual in their home while sleeping as prescribed by a physician. The FSYX™ packaging includes the durable FSYX™ pump, which connects to the FSYX™ goggles through tubing supplied with the goggles to create a vacuum system inside the goggles, and an initial supply of the FSYX™ goggles, which are fitted around an individual's eyes to create a seal.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Supplies and accessories for use with an external ocular negative pressure pump, any type, per month” to describe FSYX™ Ocular Pressure Adjusting Pump Goggles.

Medicare Benefit Category Determination

CMS determined that the FSYX™ Ocular Pressure Adjusting Pump Goggles are an accessory necessary for the effective use of the FSYX™ Ocular Pressure Adjusting Pump and published that determination on November 14, 2025.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 Code of Federal Regulations (CFR) 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions. We have not identified any comparable items to the FSYX™ Ocular Pressure Adjusting Pump Goggles, and therefore the fee schedule amounts for this item may be established using supplier price lists.

Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). The Department of Veterans Affairs (VA) National Acquisition Center (CCST) shows that the VA has a contract in place for the FSYX™ Ocular Pressure Adjusting Pump Goggles from May 15, 2025, until May 14, 2030, at a price of \$260.05 for each unit.² Using this price would result in a 2026 fee schedule amount of approximately \$167.99 per unit.

Pricing Indicator = 32

Summary of Public Feedback

Balance Ophthalmics, Inc. (Balance) agreed with the preliminary HCPCS Level II coding determination for the FSYX™ Ocular Pressure Adjusting Goggles (FSYX™ Goggles) and encouraged CMS to finalize the decision. Per Balance, the code descriptor accurately describes the FSYX™ Goggles, and it will facilitate appropriate claims processing by third-party payors. Balance also agreed with the preliminary payment determination for the FSYX™ Goggles and

² <https://www.vendorportal.ecms.va.gov/NAC/MedSurg/Details?lognumber=9015634&type=fss>

encouraged CMS to finalize that determination as well. Per Balance, the preliminary payment determination accurately reflects the novel features of the FSYX™ Goggles, such as its unique design, components, and function. Balance agreed that there is not any comparable item to the FSYX™ Goggles and that fee schedule amounts for these items should be established using the gap-fill payment methodology at 42 CFR 414.238(c), based on the \$260.05 commercial pricing for the FSYX Goggles on the VA NAC.

CMS Final HCPCS Coding Determination³

We appreciate the comments submitted in response to CMS’ published preliminary determinations. After reviewing the application and carefully considering the information provided by commenters, CMS is finalizing its preliminary coding determination to:

Establish a new HCPCS Level II code A6614, “Supplies and accessories for use with an external ocular negative pressure pump, any type, per month” to describe FSYX™ Ocular Pressure Adjusting Pump Goggles.

Final Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions. We have not identified any comparable items to the FSYX™ Ocular Pressure Adjusting Pump Goggles, and therefore the fee schedule amounts for this item may be established using supplier price lists.

Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). The VA NAC Contract Catalog Search Tool shows that the VA has a contract in place for the FSYX™ Ocular Pressure Adjusting Pump Goggles from May 15, 2025, until May 14, 2030, at a price of \$260.05 for each unit.⁴ Using this price results in a 2026 fee schedule amount of approximately \$167.99 per unit for HCPCS Level II code A6614.

Pricing Indicator = 32

³ Updated on August 14, 2026, to revise the referenced HCPCS Level II code from A6610 to A6614. This update is necessary as HCPCS Level II code A6610 has already been assigned an effective date and is currently in use.

⁴ <https://www.vendorportal.ecms.va.gov/NAC/MedSurg/Details?lognumber=9015634&type=fss>

Appendix A: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS Level II code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS Level II codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of \$150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase

fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies

Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)

Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 40 Lymphedema Compression Treatment Items

Payment is made on a purchase basis for lymphedema compression treatment items.

Pricing = 45 Customized DME

Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item

The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method).